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Dietary Factors and Type 2 Diabetes Mellitus in Urban Saudi Adults

by

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A thesis submitted in partial fulfilment of the requirements for the degree
of Doctor of Philosophy in Health Sciences

University of Warwick, Warwick Medical School

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I dedicate this thesis to my beloved parents, Ghassan Al Khudairy and Rajaa Al Sayed
for their unconditional love and for their selfless and invaluable support throughout my
course of study

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Declaration

I hereby declare that this thesis is all my own work except where I have otherwise stated and that this thesis has not been submitted for a degree at any other University.

Lena Al Khudairy

May, 2014

Abbreviations

ARR	Attributable risk reduction
AMDRs	Accepted Macronutrient Distribution Ranges
BMI	Body mass index
BRP	Biomarkers Research Program
BSR	Biomarkers Screening in Riyadh
CBHE	Cultural Barriers to Healthy Eating
CHD	Coronary heart disease
CI	Confidence intervals
DDS	Dietary diversity score
DED	Dietary energy density
F	Female
FFQ	Food frequency questionnaire
FPG	Fasting plasma glucose
GDM	Gestational diabetes mellitus
GDP	Gross domestic product
HDL-C	High density lipoprotein cholesterol
HRQOL	Health-related quality of life
HTN	Hypertension
IFG	Impaired fasting glucose
KSA	Kingdom of Saudi Arabia
LDL-C	Low density lipoprotein cholesterol
M	Male
MD	Mediterranean diet score
MOH	Ministry of health
NCEP	National Cholesterol Education Program
NDM	No diabetes mellitus
NEFAs	Non - estrefied fatty acids
NHVO	Non-hydrogenated vegetable oil
NNT	Number needed to treat
OGTT	Oral glucose tolerance test
OHG	Oral hypoglycaemic agents
OR	Odds ratio
OSOP	One sheet of paper
PA	Physical activity
PDM	Pre diabetes mellitus
PHCC	Primary health care centre
PHVO	Partially hydrogenated vegetable oil
RBG	Random blood glucose
ROS	Reactive oxygen species
SAD	Sagittal abdominal diameter
Se	Selenium
SEM	Standard error of mean values
SeP	Selenoprotein P

SR	Saudi Riyal
SR-PDM	Self-reported pre diabetes mellitus
SR-T2DM	Self-reported type 2 diabetes mellitus
SU's	Sulfonylureas
TC	Total cholesterol
T2DM	Type 2 diabetes mellitus
TG	Triglycerides
TLGS	Tehran lipid and glucose study
UA-PDM	Unaware of pre diabetes mellitus
UA-T2DM	Unaware of type 2 diabetes mellitus
UK	United Kingdom
US	United States
WC	Waist circumference
WHO	World Health Organization
WHR	Waist to hip ratio

Abstract

Background: Saudi Arabia is ranked sixth for the highest prevalence of T2DM worldwide. There is very little information on dietary factors associated with the prevalence of T2DM in Saudi Arabia. There is an urgent need for the identification of culturally specific T2DM risk factors to then develop culturally tailored public awareness programs and interventions, to reduce the prevalence of T2DM.

Objectives: To conduct a systematic review of the association between dietary factors and T2DM in the Middle Eastern region. To determine the association between dietary factors, including anthropometric measures, selected food items and beverages, selected dietary biomarkers and T2DM in Saudi adults. To identify culturally specific barriers to healthy eating in Saudi adults, with and without T2DM.

Methods: The systematic review was conducted by searching several electronic databases and contacting authors, libraries, and research centres in the Middle East. Included studies assessed potential dietary factors for T2DM in Middle Eastern adults. An existing cross-sectional survey ($n = 2631$), which is part of a larger Biomarkers Screening Survey conducted in the urban area of Riyadh, Saudi Arabia (2009), of Saudi adults aged ≥ 18 years, was used to examine the association between dietary factors and T2DM. Anthropometric measures ($n = 2355$) included body mass index (BMI), waist circumference (WC), waist to hip ratio and sagittal abdominal diameter. Selected food/beverage included 17 items collected from a food frequency questionnaire (FFQ) ($n = 1867$). The FFQ was validated in this study against two 24 hour dietary recalls ($n = 98$). Dietary biomarkers included vitamin D and selenium ($n = 567$). Barriers to healthy eating were assessed by face-to-face interviews ($n = 108$) carried out using modified pre-developed Saudi questionnaires and an additional questionnaire developed and piloted for the purpose of this study.

Results: The systematic review highlighted the large gap in evidence of associations between dietary factors and T2DM in the Middle Eastern region in general and Saudi Arabia specifically. For the cross-sectional analyses, the overall sample was 2631 adults (females: 1280, males: 1351) and the prevalence of T2DM was 29.3% (females: 25.4%, males: 32.9%). WC was associated with T2DM independently of BMI, specifically in males. The intake of dates showed an inverse association with T2DM in males. Vitamin D levels were significantly higher in females with diabetes in comparison to non-diabetics. Serum selenium was associated positively with lipid parameters in females and fasting insulin in males. However, selenium was not associated with diabetes. Lack of dietary knowledge and culturally specific barriers (lack of social support, lack of will power and reliance) were barriers to healthy eating in participants with and without T2DM.

Conclusion: The findings of this thesis highlight culturally specific factors associated with T2DM in Saudi adults. Further dietary studies in relation to T2DM are required in Saudi Arabia. Cultural issues should be incorporated when designing health awareness campaigns to address Saudis specific needs.

1 Introduction

In this chapter a brief introduction of the health problem and the structure of the thesis are presented.

1.1. Introduction

Type 2 Diabetes Mellitus (T2DM) is a significant global health burden which currently affects 8.3% of the worldwide population and is projected to rise to 8.8% by 2035 (Guariguata et al. 2013). Global estimates have shown that the Middle East as a whole, is ranked second in the world among WHO regions, for the prevalence of diabetes, with an average prevalence of 9.3% (Shaw et al. 2010). Saudi Arabia, which is located in the Middle Eastern region, is currently ranked seventh for the highest prevalence of T2DM worldwide and is expected to rank sixth by 2035 (Guariguata et al. 2013). In Saudi Arabia, the number of adults diagnosed with diabetes has increased by 1.6 million over the past 18 years (Alhowaish 2013).

Saudi Arabia is categorized as a high-income country with a gross domestic product (GDP) of 576.8 billion US dollars, and an annual growth rate of 6.8% (Bank 2011). The Ministry of Health receives 6.2% of the government annual budget (Almalki et al. 2011). The economic boost in Saudi Arabia has been paralleled by an increase in chronic conditions, mainly T2DM (Al-Shoshan 1992, Al-Nozha et al. 2004). Local studies have found that socio-economic changes are associated with diabetes prevalence which has risen from 2.5% in the 1980's (Bacchus et al. 1982) to 31.6% in 2011 (Al-

Daghri et al. 2011). However, the epidemiological evidence which has quantified diabetes prevalence and risk factors in Saudi Arabia is incomplete (Elhadd et al. 2007) which raises major concerns in terms of how to design interventions and programmes to reduce the prevalence.

Despite the high budget that is designated for free health care services in Saudi Arabia, none of the eight awareness campaigns (Prevention of Alkhurma Haemorrhagic Fever, National Campaign Against Overweight and Obesity, Combating Drug Addiction, National Campaign for Breast Cancer Awareness, Combating Tobacco Advertising and Promotion, National Campaign for Lymphoma Awareness, National Campaign Against Bird Flu (H5N1) and National Osteoporosis Awareness Campaign) run by the Ministry of Health are directed to prevent diabetes or improve dietary awareness (MOH 2012). It is extremely important to identify culturally specific risk factors associated with T2DM to inform awareness campaigns and prevent T2DM within the Saudi community.

1.2. Overview of the thesis structure

This thesis comprises 12 chapters:

- In Chapter Two (Background), an overview of Saudi Arabia's geographical and health profile is presented, to set the scene for where this study was conducted.
- In Chapter 3 (Literature review), a detailed review of the published local literature on T2DM prevalence and potential risk factors is presented.
- In Chapter 4 (Aims and objectives), the aims and objectives of this project are presented.

- In Chapter 5 (Systematic review), the first aim of this project is presented, a systematic review of the association between dietary factors and T2DM in Middle Eastern adults.
- In Chapter 6 (Survey methods), the survey methods of the Biomarkers Screening survey (2009) are presented. This project relies on data collected in the 2009 survey and therefore the methods and tools used in the 2009 survey are presented.
- In Chapter 7 (Descriptive characteristics of the 2631 participants of this project), the methods, sex-diabetes stratified descriptive findings of this project cohort and discussion of results are presented.
- In Chapter 8 (Dietary factors and T2DM: the role of anthropometric measures), the association between anthropometric measures (BMI, WC, WHR and SAD) and T2DM are presented for a subsample ($n = 2355$) of the original cohort ($n = 2631$) of the study, with the methods, findings and discussion.
- Chapter 9 (Dietary factors and T2DM: calibration study and association of selected food items with T2DM), consists of two sections. Section one covers the methods results and discussion of the food frequency questionnaire calibration study in a subsample ($n = 98$) of the original cohort ($n = 2631$). Section two covers the methods, results and discussion on the association between selected food and beverage items and T2DM for a subsample ($n = 1867$) of the original cohort of the study ($n = 2631$).
- Chapter 10 (Dietary factors and T2DM: the role of dietary biomarkers) consists of two sections on the association between dietary biomarkers and T2DM for a random subsample ($n = 567$) of the original cohort ($n = 2631$). In Section one, the results and discussion on the association between vitamin D and T2DM are

presented. In Section two, the results and discussion on the association between selenium and T2DM are presented.

- Chapter 11 (Cultural barriers to healthy eating in Saudi adults with and without T2DM) consists of two sections. Section one includes the pilot study of the questionnaires used in the study. In Section two, the methods, findings and discussion on the cultural barriers to healthy eating in adults with and without T2DM are presented for a subsample ($n=108$) of the original cohort ($n = 2631$).
- Chapter 12 (the final chapter) of this thesis covers the overall discussion of this project. The main findings of this project, strength and limitations, recommendations (policy, practice and future research), conclusions and scientific outputs are presented.

Summary

In this chapter, a brief introduction of the health problem, T2DM, was presented. The structure of the thesis was presented. In the next chapter (Chapter 2), an overview of Saudi Arabias geographical profile and the Saudi health care system will be presented.

2 Background

Introduction

In this section, the study area, including the country (Saudi Arabia) and the precise study site – Riyadh, are presented.

2.1. Country profile

Saudi Arabia, officially known as the Kingdom of Saudi Arabia, is located in the southwest region of Asia (Figure 2.1). Saudi Arabia is bordered on the North by Jordan, Iraq and Kuwait, on the west by the Red Sea, on the south by Yemen and Oman, and on the east by the United Arab Emirates and Qatar (Figure 2.2.). The capital city is Riyadh, located in the central province of Saudi Arabia (Figure 2.2.). The size of the country is around 2, 000, 000 km² (WHO 2011) where nearly half of it is covered by desert, and the mountains in the west of Saudi Arabia are very rich in minerals. The eastern region has the richest reservoirs of oil in the world. Arabic is the official language in Saudi Arabia (MOFA 2006). Saudi Arabia has a dry hot climate with temperatures ranging between 34.4–42.7°C during summer season, and 12.1–22.5°C during winter season (Nofal et al. 1997).

The World Health Organization (WHO) estimated Saudi Arabia's population to be at approximately 28,288 million in 2009 (WHO 2009). Around 68% of the population are Saudi nationals (CDSI 2010), the annual growth rate of the total population is 3.2%,

and around 85% of the population is urbanised. Saudi Arabian nationals have a life expectancy at birth of 73.8 years, and females have a slightly higher life expectancy (75.1 years) in comparison to males (72.7 years) (WHO 2011).



Figure 2.4. The location of Saudi Arabia in the Middle Eastern region (Atlas 2013).



Figure 5.2. The map of Saudi Arabia showing the capital city – Riyadh (the study area) (Atlas 2013).

Saudi Arabia's capital city is Riyadh, located in the centre of the country (figure 2.2.) and the second largest province in Saudi Arabia (MOI 2004). Around 6 million of the total population resides in Riyadh, with an annual growth rate of 2.9%. Around 68.3% of the residents are Saudi nationals, and the sex distribution is 51% males and 49% females. The majority of Riyadh residents (around 60%) are over the age of 15 years (figure 2.3), and 60.2% of them are married with a mean family size of 5.09 individuals (MEO 2004).

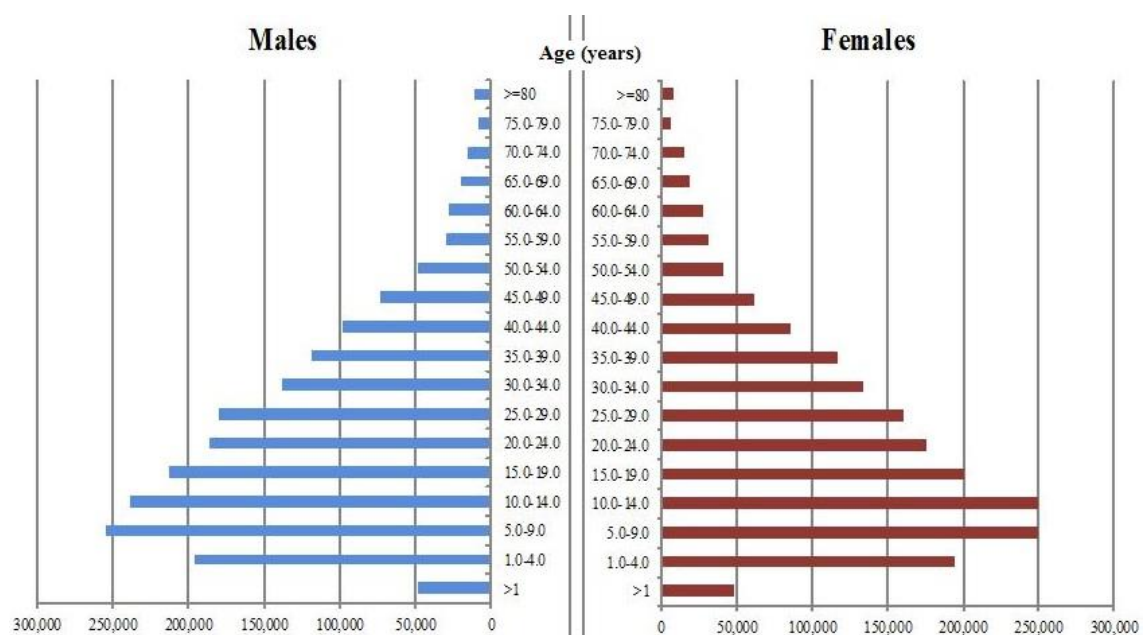


Figure 2.6. Population pyramid of Saudi nationals in Riyadh, Saudi Arabia (MEO 2004).

2.2. The health care system in Saudi Arabia

Saudi Arabia is categorised as a high-income country with a gross domestic product (GDP) of 576.8 billion US dollars and an annual growth rate of 6.8% (Bank 2011). The total health care expenditure is around 4% of the total country's GDP (WHO 2011). The first public health and ambulance department was established in 1925 in Saudi Arabia. The Ministry of health (MOH) was established in 1950 to deliver healthcare services,

promote general health, prevent diseases, promote health research, monitor health institutions, provide training in the health sector, and regulate the private and governmental health sectors in Saudi Arabia (MOH 2012). The Saudi health care system has improved over the years, and is ranked 26th according to the WHO health care system ranking. The Ministry of Health receives 6.2% of the annual government budget (Almalki et al. 2011).

The Ministry of Health has a total of 244 hospitals and 2037 primary health care centres (PHCC's) around the Kingdom (Almalki et al. 2011). The number of physicians per 10,000 individuals in governmental health sectors is 10.2, which is around one doctor per 982 individuals. Approximately 44 governmental hospitals are located in Riyadh, and 377 PHCC's are distributed around the city. The governmental health services fall under the Ministry of Health management system and all health services are completely free of charge (MOH 2009).

Summary

In this chapter, a brief overview of Saudi Arabia, and its capital city Riyadh where this study was conducted, and the healthcare system in this region were presented. In the next chapter (Chapter 3), the literature review of local Saudi studies on T2DM prevalence and potential risk factors in Saudi Arabia will be presented.

3 Literature review

Introduction

In this chapter a review of published Saudi studies on type 2 diabetes prevalence and potential risk factors will be presented.

3.1. Overview on the prevalence of Type 2 diabetes in Saudi Arabia

The Kingdom of Saudi Arabia is located in the Arabian Peninsula and is considered the largest developing country in the Gulf Area (Shaw et al. 2009). The economic growth in Saudi Arabia was associated with socio-economic changes, such as rapid urbanization, decrease in infant mortality and increase in life expectancy (Alhowaish 2013). The socio-economic changes have imposed a heavy burden of non-communicable diseases in Saudi Arabia, specifically type 2 diabetes mellitus (T2DM) (El-Hazmi et al. 1998, Al-Nozha et al. 2004, Elhadd et al. 2007, Al-Daghri et al. 2011). Diabetes is a manmade degenerative disease (Omran 1983) and a global health burden which is currently affecting 382 million adults (8.3%) worldwide and is projected to rise to 8.8% by 2035 (Guariguata et al. 2013). A significant proportion of this increase will be observed in developing countries (Shaw et al. 2009). Global estimates have shown that the Middle East as a whole, is ranked second in the world among WHO regions, for the prevalence of diabetes, with an average prevalence of 9.3% (Shaw et al. 2010). Saudi Arabia is currently ranked seventh for the highest prevalence of T2DM worldwide and is expected to rank sixth by 2035 (Guariguata et al. 2013).

In Saudi Arabia, diabetes prevalence has dramatically shifted from a non-significant health problem in the early 1980's to an emerging chronic condition over the past few decades (Elhadd et al. 2007). The prevalence will continue to escalate in the next two decades and Saudi Arabia will have one of the highest diabetes prevalences (Shaw et al. 2009, Guariguata et al. 2013). Local studies found that socio-economic changes are associated with the on-going increase in diabetes prevalence from 2.5% in the 1980's (Bacchus et al. 1982) to 31.6% in 2011 (Al-Daghri et al. 2011). However, the epidemiological evidence that quantified diabetes prevalence is incomplete (Table 3.1.). For instance, two studies limited their sample to males and rural areas (Bacchus et al. 1982, Fatani 1987) whilst two surveys studied an urbanised population (Anokute 1992, Al-Daghri et al. 2011). Methods to diagnose diabetes also varied between studies (Bacchus et al. 1982, Anokute 1992, El-Hazmi et al. 1996, Al-Nuaim et al. 1997, El-Hazmi et al. 2000, Al-Nozha et al. 2004).

The prevalence of diabetes has been clearly studied in the Saudi literature, and has been shown to increase over time, yet well designed studies with stronger methodology are required to overcome the variation in diabetes prevalence estimates for similar time periods (Al-Nozha et al. 2004, Elhadd et al. 2007). Overall, Saudi Arabia is among the highest for the prevalence of T2DM in comparison to neighbouring countries in the Gulf region (Table 3.2.).

Table 3.1. Epidemiological studies on the prevalence of T2DM in Saudi Arabia

Reference	Sample size	Sex	Age	Area	Diagnosis	Prevalence
(Bacchus et al. 1982)	1385	Males	> 15	Rural	OGTT	2.5%
(Fatani et al. 1987)	5222	Both	All	Rural	RBG/OGTT	4.3%
(Anokute 1990)	3158	Males	> 15	Urban	Urine/FPG	6.0%
(El-Hazmi et al. 1996)	23493	Both	2-77	Both	FPG/OGTT	5.5%
(Al-Nuaim 1997)	13177	Both	≥ 15	Both	RPG/OGTT	10.5%
(Warsy et al. 1999)	14660	Both	>14	Both	FPG/OGTT	5.0%
(Al-Nozha et al. 2004)	16917	Both	30-70	Both	FPG	23.7%
(Al-Daghri et al. 2011)	9149	Both	7-80	Urban	FPG	31.6

OGTT indicates oral glucose tolerance test; **RBG** indicates random blood glucose test; **FPG** indicates fasting plasma glucose test.

Table 3.2. The prevalence of T2DM in Gulf countries

Reference	Country	Sample size	Prevalence (%)
(Bener et al. 2009)	Qatar	1117	Overall: 16.7% Females: 18.1% Males: 15.2%
(Al-Habori et al. 2004)	Yemen	498	Overall: 4.6% Females: 2.0% Males: 7.4%
(Abdella et al. 1998)	Kuwait	3003	Overall: 14.8% Females: 14.8% Males: 14.7%
(Al-Moosa et al. 2006)	Oman	5840	Overall: 11.6% Females: 11.3% Males: 11.8%
(Al-Mahroos et al. 1998)	Bahrain	2029	Overall: 29.4% Females: 14.4% Males: 14.9%
(Saadi et al. 2007)	United Arab of Emirates	2396	Overall: 10.2% Females: 11.1% Males: 9.4%

Up to date information on the profile of diabetes in Saudi Arabia is currently not available. An earlier national epidemiological survey (1995-2000) which used fasting plasma glucose levels (FPG) for diabetes diagnosis ($\text{FPG} \geq 7.0 \text{ mmol/L}$, equivalent to 126 mg/dL) in 16917 Saudi adults described the diabetes profile in Saudi Arabian adults (Al-Nozha et al. 2004) and is presented in Table 3.3.

Table 3.3. Diabetes profile in Saudi Arabia (Al-Nozha et al. 2004)

Saudi Population	Prevalence (%)
Diagnosed with Diabetes Mellitus	23.7%
Unaware of their Diabetes	27.9%
Males	26.2%
Females	21.5%
Age	
30-39 years old	12.1%
40-49 years old	23.0%
50-59 years old	33.8%
60-70 years old	36.5%
Males with Central Obesity	33.1%
Females with Central Obesity	27.0%
Residence	
Rural Population	25.5%
Urban Population	19.5%
Region	
Central	23.7%
Northern	27.9%
Southern	18.2%
Western	24.7%
Eastern	26.4%

3.2. Complications and co-morbidities

Similarly to the rest of the world's diabetes population, T2DM is the most prevalent form in the Saudi population (Famuyiwa et al. 1992, Elhadd et al. 2007). T2DM

predisposes individuals to a higher risk of macro and micro vascular complications (Del Prato et al. 2009, Meo 2009). Saudi's with T2DM have a significant number of disease related complications (Alwakeel et al. 2008).

The complications of T2DM among Saudi Arabian adults have been examined in 1952 patients who were regularly followed up in the Security Armed Forces Hospital in the capital city of Saudi Arabia, Riyadh (Alwakeel et al. 2008). The data were obtained from medical records from January 1989 - January 2004. The results showed that cardiovascular and renal complications were the most prevalent (Table 3.4). The authors of this study suggested that the factors behind the increased numbers of complications were sedentary lifestyle, unbalanced diet, consanguinity, genetics and lack of awareness. In addition to the high number of disease related complications, multiple complications in patients were surprisingly frequent (Alwakeel et al. 2008).

Table 3.4. Common complications of T2DM in Saudi Arabia (Alwakeel et al. 2008)

Complication	Prevalence
Nephropathy	32.1%
Acute coronary syndrome	23.1%
Cataracts	22.9%
Retinopathy	16.7%
Myocardial infraction	14.3%
Doubling of serum creatinine	12.8%
Hypertension	78.1%
Dyslipidemia	39.1%
Overall mortality	8.2%

The high number of diabetes related complications is associated with decreased health-related quality of life in Saudi individuals. One cross-sectional study assessed health-related quality of life (HRQOL) in adults with or without T2DM. The study focused on physical and mental health (i.e. physical pain, emotional problems) using a 12 items

questionnaire (SF-12 questionnaire). Results showed that females with diabetes and participants with uncontrolled diabetes reported lower HRQOL scores. Female's frequent admissions to the emergency departments decreased their HRQOL; such admissions were mainly caused by hyperglycaemia. The study revealed a number of factors that were associated with poor HRQOL in Saudi patients with T2DM such as family history, elevated fasting blood glucose levels, obesity and hyperglycaemia (Al-Shehri et al. 2008).

3.3. Potential risk factors for the increased prevalence of diabetes in Saudi Arabia

The rapid economic boost in Saudi Arabia has shifted the disease structure from communicable to degenerative diseases (Guy et al. 2009). Modifiable risk factors for diabetes have been identified and examined within the Saudi context, but despite this, the general knowledge of the Saudi population regarding diabetes and related risk factors is generally poor (Abu-Zeid et al. 1992, Azab 2001, Al-Arouj et al. 2010). Aljoudi and colleagues interviewed 288 patients with diabetes to measure their knowledge of diabetes associated risk factors. The authors found that more than 50% of the patients failed to correctly identify diabetes risk factors, such as inactivity and smoking (Aljoudi et al. 2009). However, obesity was the most common risk factor (35.8%) identified by patients. Although Aljoudi associated poor knowledge with low education levels (Aljoudi and Taha 2009), Abahussain argues that poor diabetes knowledge was evident among educated Saudi adults (Abahussain et al. 2005). Interestingly, the main source of diabetes information among 2007 Saudi adults was from friends and family (73.8%) whilst health care professionals represented the lowest source of information (19.1%) (Mohieldein et al. 2011).

A number of socio demographic factors have been suggested by researchers to account for the increasing prevalence of diabetes in Saudi Arabia. Urbanization and the vast economic growth are those most frequently referred to (Al Majwal et al. 2009). Urbanization and the rapid rush in development has led to the adaptation of a westernised lifestyle; the market for fast food restaurants and supermarkets has markedly expanded (Yagob Y. Al-Mazrou 2004). A family's income has notably improved over the years, which has led to the growth of a disposable income. Lifestyle changes have strongly influenced Saudi habits as frequent dining at restaurants has become part of the Saudi culture (Hijazi et al. 2000, Musaiger 2004, Amin et al. 2008). Inactivity is becoming increasingly common in the Saudi population. It is economically affordable to a large proportion of the population to have their own car and therefore most of people drive to work (Al- Hazzaa et al. 2007). Walking is extremely rare in Saudi Arabia, the infrastructure of the country does not facilitate outdoor activity. The hot climate decreases the desire to walk and cultural restrictions limit women's walking habits. It is common for women to carry out social gatherings where restaurant meals or homemade snacks high in sugar and fat are served (Al-Othaimeen et al. 2007). Maternal occupation has increased over the past decades (Al-Assaf et al. 2007) which increases the ability to hire help in household work and engage in an inactive lifestyle (Al-Othaimeen et al. 2007).

Urbanization

In Riyadh, the number of inhabitants increased from 30000 in the 1950's (Mubarak 2004) to around 6 million in 2004. Around 68.3% of the residents are Saudi nationals, and the sex distribution is 51% males and 49% females. The majority of Riyadh

residents (around 60%) are over the age of 15 years, and 60.2% of them are married with a mean family size of 5.09 individuals (MEO 2004). Saudi Arabia was established in the early 1930's and has experienced a vast development since then. For instance, the suburbanization process in Riyadh parallels the suburban development of Westernized countries (Mubarak 2004). In the 1970's in Saudi Arabia, also known as the "Golden decade", the oil boom, economic development and rapid urbanization were associated with lifestyle changes and mainly in dietary intakes. From the 1970's to the 1980's caloric consumption increased from 1,800 kcal per day to more than 3,000 kcal per day and was accompanied by an increased fat consumption as high as 95 gm per capita/day. Similarly, total meat intake increased from 22kg to 60 kg per capita/year and sugar intake increased from 16.1 kg to 28.1 kg per capita/year (Al-Shoshan 1992). Dietary changes have been accompanied by an increase in nutrition-related health conditions, mainly diabetes, as a result of this nutritional transition (Al-Shoshan 1992, Nielsen 1999).

Diabetes prevalence varies among different regions (Figure 3.1.). Rural areas have lower diabetes prevalence (19.5%) in comparison to urban regions (25.5%) (Al-Nozha et al. 2004). Urban individuals are less active in comparison with rural inhabitants, due to a westernised lifestyle, which can be associated with increased diabetes rates. Researchers have suggested that obesity, decreased physical activity, westernised diet and lifestyle might account for the substantial differences in diabetes prevalence amongst Saudi regions. In other words, urbanization seems to considerably increase diabetes mellitus in Saudi Arabia (Al-Nozha et al. 2004).

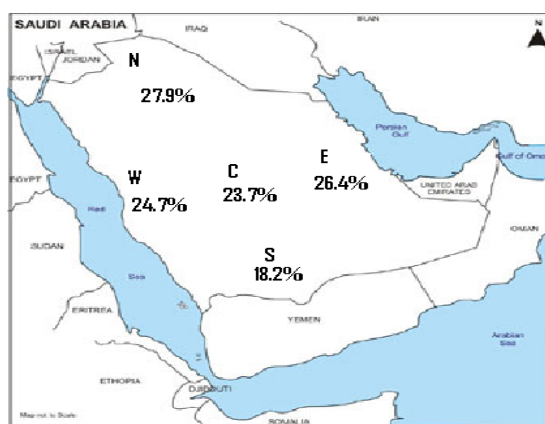


Figure 3.1. Diabetes prevalence among Saudi regions (Al-Nozha et al. 2004), Symbols N=North, S=South, W=West, E=East, C=Central.

Consanguinity

Consanguineous marriages are common among Saudi families for various reasons; some families believe that such marriages ensure that money, properties, traditions and culture would safely remain within the family. Other families believe that divorce is uncommon in such marriages since both parties were raised in the same culture, therefore the marriage environment will remain the same and adjustment will be easier (El-Hazmi et al. 1995, Elhadd et al. 2007). In the early 90's, Anokute suggested an association between T2DM and the high levels of consanguinity in 210 diabetic cases. However, this study was a retrospective study with a relatively small number of cases (Anokute 1992).

El-Hazmi and colleagues confirmed the high rates of consanguineous marriages at higher than 55% in the Saudi population. More than 25% of such marriages were associated with the first cousin and nearly 15% were to a distant relative (El-Hazmi et al. 1995). However, Elhadd questions the association between consanguinity and the prevalence of T2DM since the available epidemiological evidence has not measured

consanguinity and large epidemiological studies are currently lacking (Elhadd et al. 2007).

Obesity

Obesity is a traditional major risk factor for the development and progression of T2DM (Steppan et al. 2001) globally. Obesity is associated with a number of chronic conditions and especially T2DM. Non - estrefied fatty acids (NEFAs) are released by adipose tissues to modulate metabolism. NEFAs are one of the main factors in modulating insulin sensitivity. However, in obese individuals the release of NEFAs is increased and high levels are observed. Increased levels of NEFAs are associated with insulin resistance and impaired β -cell function which accelerates the progression and development of T2DM. Given this, factors such as consumption of an energy dense diet and decreased physical activity are the main reasons for obesity and T2DM epidemics (Boden et al. 2002, Kahn et al. 2006). A certain pattern of fat distribution with increased weight seems to be associated with a higher risk of T2DM (Boyko et al. 2000, Samras et al. 2000). Individuals with increased abdominal fat, also known as central obesity, have increased insulin levels and higher insulin resistance when compared with individuals with peripheral adiposity (Samras and Campbell 2000, Laaksonen et al. 2003, Parillo et al. 2004).

Observational studies have confirmed that Saudi's with prevalent diabetes are more likely to be either overweight or obese, and that obesity may play a role in the increasing prevalence of T2DM (El-Hazmi et al. 1999, Al-Nozha et al. 2004, Al-Daghri et al. 2011). The prevalence of obesity is significantly lower in rural settings (27.0%) in comparison to urban settings (39.7%). For instance, the Southern region has the lowest

prevalence of obesity (29.9%) in comparison to the Northern (37.0%), Central (40.0%), Eastern (42.2%) and Western (32.7%) province (Al-Nozha et al. 2005). Residents of the Southern region of Saudi Arabia engage in a more rural lifestyle which includes higher levels of activity and healthier eating habits (Al-Nuaim et al. 1997, Al-Nozha et al. 2005).

The mean body mass index (BMI) of Saudi females, aged 15-64, is 29.1 kg/m² whilst the mean waist circumference (WC) is 82.9 cm. On the other hand, males seem to have a lower BMI (27.0 kg/m²) but a higher WC (89.6 cm) (Al-Hamdan NA et al. 2005). Over the years, the prevalence of obesity has increased from 22.1% (Al-Nuaim et al. 1997) to 35.6% among Saudi adults (Al-Nozha et al. 2005). More recently researchers believe that 74.6% of the Saudi population are either obese or overweight (Al-Nozha et al. 2005).

National studies have been carried out to measure the prevalence of overweight and obesity in the Saudi population. The National Nutritional survey (1985-1998) examined the prevalence of obesity in 17892 Saudi nationals aged 18-60 years. In females, the prevalence of overweight and obesity was 28.4% and 26.6% respectively while in males the prevalence was 30.7% and 23.6% respectively (Al-Othaimeen et al. 2007). Furthermore, more recent data from the National Epidemiological Health Survey ($n = 17232$) reported alarming obesity figures among Saudi adults. Over 36.0% of the Saudi population were overweight (31.8% of females and 42.4% of males), whilst 35.6% of the population were obese (44% of females and 26.4% of males) (Al-Nozha et al. 2005). Nevertheless, Saudi national surveys to date have measured BMI alone, therefore additional anthropometric measures on a national level are currently lacking.

A recent study has assessed risk factors for T2DM in 603 Saudi adults aged 40-74 years. The self-administered Canadian Risk questionnaire was used to assess risk factors. The results showed that over 42% of females had a BMI ≥ 30 kg/m² whilst 50% of males were overweight (BMI 25-29 kg/m²). Over 50% of participants had a high WC, > 88 cm in females and > 102 in males (Alghadir et al. 2014). However, the sample was fairly small and anthropometric measures were based on self-reports. The associations between traditional anthropometric measure, such as waist to hip ratio and sagittal abdominal diameter, and the prevalence of T2DM have not been examined within the Saudi context (Ng et al. 2011). Overall, epidemiological evidence that originates from Saudi Arabia suggest that obesity and an unhealthy lifestyle are the two main risk factors associated with the high occurrence of T2DM (Al-Nozha et al. 2004, Al-Nozha et al. 2005, Al-Othaimeen et al. 2007, Elhadd et al. 2007). However, further investigations are required since the available evidence originates from descriptive findings and disease-risk factor associations have not been properly explored.

Nutrition

The diet-disease association, including diabetes, has received a great deal of international attention, accompanied by methodological efforts to assess dietary intake accurately (Willett 1998). It has been well established that increased calorie intake increases the risk of T2DM by increasing body weight, thus decreasing insulin sensitivity. Therefore dietary intake, such as macronutrients, micronutrients, food intake, beverage intake and dietary patterns have been identified as risk factors for T2DM (Parillo and Riccardi 2004).

Food and beverage intake status among Saudi adults

International evidence has identified a number of dietary items that may play a role in the risk of T2DM. For instance, the refining process of carbohydrates increases caloric density and decreases dietary fibre. Therefore, refined carbohydrates may increase the risk of T2DM by increasing insulin resistance (Gross et al. 2004). Similarly, a higher consumption of eggs have been shown to be associated with an increased risk of T2DM (Tran et al. 2014), where the nutritional composition of an egg is high in cholesterol and saturated fat (Djoussé et al. 2009). Some nutritional studies have suggested an association between added sugar and the risk of T2DM (Montonen et al. 2007, Hu et al. 2010, Romaguera et al. 2013). Sugar, often referred to as empty calories, can be associated with diabetes by inducing weight gain and therefore insulin resistance (Johnson et al. 2009). Another potential mechanism is that sugar rapidly increases blood glucose and insulin levels which contribute to a higher glycaemic load and therefore inducing weight gain, glucose and insulin intolerance (Hu and Malik 2010).

On the other hand, protective foods against diabetes have been identified, such as whole-grain rich foods, green leafy vegetables, and cereal fibre (Carter et al. 2010, Sluijs et al. 2010, Sun et al. 2010). The composition of protective foods (*i.e.*, fibre, vitamins and minerals) may reduce the risk of T2DM by decreasing inflammation, improving glucose metabolism, endothelial function, and insulin sensitivity (He et al. 2010). Nutritional evidence has also identified some potential protective beverages against T2DM, such as coffee (Ding et al. 2014) and low fat milk consumption (Choi et al. 2005). Similarly to foods, the nutritional composition of protective beverages may play a role in protecting against T2DM. For instance, chromogenic acid, a major component of coffee, may decrease the risk of diabetes by reducing glucose absorption, liver glucose output and

oxidative stress (Ding et al. 2014), whilst milk contains dairy protein and lactose that may reduce weight gain by enhancing satiety and therefore reducing the risk of T2DM (Choi et al. 2005).

Diet-related chronic conditions, such as diabetes, represent a major public health concern in Saudi Arabia (Musaiger 2004, Al-Othaimeen et al. 2007, Elhadd et al. 2007). The economic boost and rapid urbanization have accelerated the nutritional transition where energy-dense, refined carbohydrates and fat-saturated cuisine has replaced the traditional diet (Musaiger et al. 2012). In Saudi Arabia, the traditional macronutrient consumption used to be derived from wheat, legumes, dates, and vegetables. Over the past few decades, nutritional intake has shifted from a high-fibre diet to an “energy dense-fatty diet.” Earlier ecological data of food consumption have quantified macronutrient changes in Saudi Arabia. From the 1960s till the 1980s, caloric consumption increased, from 2,000 kcal per day to more than 3,000 kcal per day, and this was accompanied by an increased fat consumption as high as 95 gm per capita/day (Al-Shoshan 1992, Nielsen 1999). Recent reports showed that the mean fruit consumption among Saudi adults is lower than 4 servings/week. Over 60% of Saudi adults consume less than one fruit serving per/day. Similar reports were found for vegetable intake where 50% of Saudi adults consume less than one serving per day. The majority reported the use of vegetable oil (83.4%) whilst only 1.7% reported the use of olive oil (Al-Hamdan NA et al. 2005).

Saudi Arabia has seen a growing market of fast-food restaurants, fatty snacks, and soft drinks. Over-nutrition has become a widespread habit with an increased calorie intake consumed mainly from fat (Zaghloul et al. 2010). This nutritional transition has paralleled the increase in lifestyle-related chronic conditions, such as diabetes (Al-

Shoshan 1992, Amuna et al. 2008). However, evidence linking these dietary habits to the emerging diabetes epidemic is not clearly defined within the Saudi context and studies examining the diet-disease association are very scarce (Nielsen 1999, Al Majwal et al. 2009, Ng et al. 2011, Amini et al. 2012).

Al Assaf and Al Numair (2007) published the first study which assessed nutritional intake in Saudi males using a three-day food record. The researchers recruited (personally and/or through advertisement) 170 healthy Saudi adult males. Half of the sample lived in urban areas and the other half lived in rural locations around the city of Riyadh. Adults who were unhealthy and/or consumed dietary supplements were excluded from the study. Participants received a questionnaire to evaluate their dietary habits and activity and kept a food record for three consecutive days (two weekdays and one weekend) following instruction and a one-day trial. The findings showed that the majority of the sample (90%) regularly consumed rice, wheat bread and dates, while less (70%) consumed meat (camel), poultry, broad beans and fruits. The most commonly consumed beverages were buttermilk, Arabic coffee and sweet black tea, followed by carbonated soft drinks (Al-Assaf and Al-Numair 2007). This study found that macronutrient consumption fell within the Accepted Macronutrient Distribution Ranges (AMDRs). However, this was not the case for some macro and micronutrients. For instance, increased intakes of saturated fat and decreased intakes of vitamin D and calcium were observed. Higher income, inactivity and poor dietary knowledge were also associated with increased body weight. However, the study was limited to males that lived in Riyadh and included a fairly small number of participants which limits the generalizability of the findings (Al-Assaf and Al-Numair 2007). Moreover, a three days food record does not represent usual intake. Additionally, the process of recording food intake may have influenced participants dietary intake and therefore may have

introduced some bias (Willett 1988). Nevertheless, this study is one of the very few that provides some insights of Saudi dietary habits.

The associations between dietary factors and T2DM have not been studied until recently within the Saudi context. Midhet and colleagues published the first study which assessed the effect of dietary intake on the risk of T2DM. The case control study included 283 T2DM cases and 215 healthy controls. The sample included native Saudi male and female adults aged between 30-70 years followed up in primary health care clinics (PHCC's) in Al- Qassim city. Dietary intake was assessed using a food preference questionnaire and a 24 hour dietary recall. Cases were asked about their diet before they developed diabetes. The findings showed that routine consumption of certain foods such as Kabsa (Odds Ratio, (OR) 5.5, 95% Confidence intervals (CI): 2.3–13.5), bakery items (OR 2.4, CI: 1.3–4.6), and French fries (OR 2.2, CI: 1.2–3.9) increased the risk of T2DM. Notably, fish consumption was associated with an increased risk of diabetes (OR 2.5, CI: 1.3–4.7). Routine consumption of vegetables showed a protective effect for the risk of T2DM (OR 0.4, CI: 0.2–0.7) (Midhet et al. 2010).

Midhet et al. was the first published study which aimed to examine dietary habits in relation to T2DM in Saudi adults. However, the findings should be interpreted with caution due to some methodological limitations. For instance, a one 24 hour dietary recall does not capture usual intake, and there was no justification of the inclusion of the specific food items studied (Midhet et al. 2010). The association between fish intake and T2DM risk is questionable; as fish intake (baked or broiled) is associated protective health outcomes (Meyer et al. 2001, Mozaffarian et al. 2010). It is likely that fish was consumed with other food items; however that was not clarified in the study. The

associations were based on frequency of intake alone rather than frequency and amount, therefore the observed associations may be exaggerated. The sample was fairly small and limited to a small city in Saudi Arabia. Overall, this study highlights the need for well designed nutritional studies in relation to diabetes within the Saudi context.

Micronutrient status among Saudi adults

Not only has dietary status as a whole, been poorly studied in Saudi individuals, but similarly micronutrient status has not been extensively evaluated (Al-Saleh 2000, AL-Daghri et al. 2010). Several international studies have evaluated the potential health benefits of micronutrients, particularly antioxidant intake in the prevention and treatment of T2DM (Anderson et al. 2001, Evans et al. 2002, Faure 2003). Specifically, recent findings have highlighted the potential role of some micronutrients such as vitamin D and selenium in the development of T2DM (Mattila et al. 2007, Knekt et al. 2008, Stranges et al. 2010). Altered micronutrient levels in humans lead to cellular damage which is associated with oxidative stress and inflammation (Evans et al. 2002, Evans 2007, Garcia-Bailo et al. 2011). Oxidative stress play a role in the risk of T2DM by either decreasing the antioxidant defence mechanism (Merzouk et al. 2003), or by the increased production of free radicals which causes inflammation (Lamb et al. 2008), or by both (Garcia-Bailo et al. 2011).

The role of vitamin D in T2DM was proposed following the presence of vitamin D receptors in the pancreatic β -islet cells (Maggin et al. 2007). The active form of vitamin D in the β -islet cells acts on vitamin D receptors and enhances the production and secretion of insulin (Holick 2008). The role of vitamin D in maintaining bone tissue and calcium/phosphate homeostasis has been well established (Pittas et al. 2007).

Observational studies have investigated the role of low vitamin D levels and risk of T2DM (Pittas et al. 2007, Wolden-Kirk et al. 2011). There are several potential mechanisms that may explain the association between low vitamin D levels and T2DM. Low vitamin D levels are associated with impaired β cell function by altering the insulin response to glucose stimulation (Wolden-Kirk et al. 2011). Low vitamin D levels are also associated with decreased insulin sensitivity or impaired insulin secretion or both (Scragg 2008). Vitamin D controls the generation of cytokines which eventually improve β cell function, therefore, decreased levels of vitamin D may alter this mechanism and contribute to β cell dysfunction (Pittas et al. 2007, Pittas et al. 2007).

Findings from observational studies in Saudi Arabia have shown that Saudi individuals suffer from severe vitamin D deficiency (Sedrani et al. 1983, Fonseca et al. 1984, Al Faraj et al. 2003). Traditional clothing, avoidance of sun exposure and westernized dietary patterns may play a role in vitamin D deficiency in Saudi individuals (Sedrani et al. 1983). There is only one study that has evaluated the association between vitamin D levels and T2DM in Saudi adults (AL-Daghri et al. 2010). The cross-sectional study included 341 adults, 177 without T2DM and 164 with T2DM. Individuals without T2DM had lower levels of vitamin D (17.9 nmol/L) in comparison to individuals with T2DM (26.9 nmol/L) (AL-Daghri et al. 2010). Nonetheless, hypovitaminosis, vitamin $D \leq 80$ nmol/L (Hollis 2005), was prevalent among Saudi individuals with and without T2DM. The findings are in contrast with international observations where serum vitamin D levels are lower in diabetics in comparison to no-diabetics (Scragg et al. 1995, Yoho et al. 2009). The study included participants with diagnosed diabetes, and in Saudi Arabia multivitamin supplementation is part of the treatment plan of T2DM, which may explain the findings. Nevertheless, the study highlights the extremely low levels of vitamin D in Saudi adults and the associations with T2DM warrants further

investigation (AL-Daghri et al. 2010). Interestingly, a recent study showed that vitamin D levels are higher during winter time rather than summer in Saudi individuals (Al-Daghri et al. 2011), extremely high temperatures during the summer time may explain these findings as Saudi's avoid sun exposure during the summer time.

On the other hand, Saudi individuals seem to have high levels of other micronutrients, such as selenium. In 743 healthy Saudi adults the mean levels of selenium were 107.04 µg/l (Al-Saleh et al. 2007), these levels are comparable to countries with high selenium status such as Lebanon (142 ng/ml) (Obeid et al. 2008), US (125.7 ng/ml) (Bleys et al. 2008), Canada (115 ng/ml) (Gibson et al. 1985), and Japan (107 ng/ml) (Imai et al. 1990). In contrast to vitamin D, elevated serum selenium levels seem to increase the risk of T2DM (Bleys et al. 2007). Recent studies from the U.S. have found that higher selenium levels are associated with adverse health outcomes such as an elevated glucose profile (Laclaustra et al. 2009, Akbaraly et al. 2010), and a higher risk of T2DM (Laclaustra et al. 2009, Stranges et al. 2010).

The role of selenium in maintaining thyroid function, immune function and antioxidant defence mechanism has been well established (Brown et al. 2001). However, high selenium levels can generate reactive oxygen species (ROS) that dramatically increase in oxidative stress conditions. ROS may affect β cell function by increasing insulin resistance (Bleys et al. 2007). Plasma selenium is incorporated in selenoprotein P (SeP) (Brown et al. , Stranges et al. 2010), a transport protein for selenium, which is mainly produced by the liver (Misu et al. 2010). Increased levels of SeP are associated with insulin resistance in skeletal muscles and the liver. Elevated levels of SeP are positively associated with increased fasting plasma glucose and HbA1c (Misu et al. 2010).

The association between serum selenium levels and T2DM has not been studied within the Saudi context. The available literature indicates that Saudi individuals have selenium levels and intakes (75–122 µg/person/day) (Al-Ahmary 2009) comparable to those of selenium-replete populations (Al-Saleh et al. 2007) such as the US, which have been associated with potential diabetes risk (Laclaustra et al. 2009). It seems that there are geographical variations in selenium levels in the soil in different regions of Saudi Arabia (Al-Saleh 2000). Wheat grains grown in the northern area have the highest selenium content (mean range 285.5 µg/kg) in comparison to other regions of Saudi Arabia (Al-Saleh et al. 1997). Interestingly, the northern region also has the highest prevalence of diabetes (27.9%) in Saudi Arabia (Al-Nozha et al. 2004). Over-nourishment in Saudi adults may play a role in the association between selenium levels and T2DM, however, this association is currently unclear and warrants further investigation within the Saudi context (Al-Saleh 2000). Modifiable lifestyle factors such as physical activity, and specific nutritional aspects, such as vitamin D deficiency (Maxwell et al. 2011) and high selenium status may increase the risk of T2DM (Stranges et al. 2007). Current evidence suggests that examining nutritional biomarkers which are associated with T2DM may have public health benefits by serving as predictors of early risk of T2DM (Badawi et al. 2010).

Studies identified to date have suggested some dietary factors are possibly associated with the high prevalence of T2DM in Saudi Arabia. However, the cultural context may have influenced dietary intake. It is well established that eating behaviours and nutritional knowledge are different between nations and within nations and that this is influenced by cultural backgrounds (Smith et al. 1995, Kearney et al. 2000, Bihan et al. 2010). It follows that the Saudi culture may have an influence on the population's health awareness, eating behaviours and attitude towards nutrition.

Saudi cultural factors and dietary behaviours

The ‘Arab’ cultural, social, and lifestyle patterns are very different to those in Western societies (Lipson et al. 1983). Saudi individuals with health conditions believe that the occurrence of a disease is God’s will and predestination from God. They also hope that illness or disease can erase a person’s sins (Lipson and Meleis 1983, Gallagher et al. 1985). The cultural perception of health related conditions does not necessary stop them from seeking medical treatment, yet such beliefs help them cope with their health conditions (Al-Shahri 2002).

‘Hospitality’ is another area where differences are seen between Arab and Western societies. Hospitality is not linked to social class or wealth in Saudi Arabia. Frequent social occasions such as family gatherings, weddings and holy days (e.g. Ramadan) require displays of hospitality which mainly include large amounts of food. Hospitality in Saudi Arabia includes extensive greetings, insistence, emphasis, and assistance to join their occasion and eat (Ellen 1997). It is very common for Saudi women to frequently carry out social gatherings accompanied by restaurant meals and/or homemade snacks that are high in sugar and fat (Al-Othaimeen et al. 2007).

Inactivity and over-nutrition are some peculiar aspects of the Saudi culture (Al-Nozha et al. 2004), accompanied by poor nutritional knowledge. Bani and Hashim evaluated the nutritional knowledge in 393 Saudi adults (≥ 16 years of age). Participants completed a questionnaire which assessed their nutritional knowledge for coronary heart disease. Males were more aware of high dietary cholesterol foods in comparison to females. However, participants were not able to differentiate between animal fat and vegetable

fat. Additionally, 30% of participants classified rice as a cholesterol food item while 70% believed that liver was a cholesterol-free food (Bani et al. 1999).

Another study has evaluated misconceptions about diabetes in 1039 individuals with diabetes in Mecca, Kingdom of Saudi Arabia (KSA) (Al-Saeedi 2001). The study reported high rates of misconceptions among participants. For instance, 39% reported treatment misconception and 23% believed that they can eat freely as long as they take their medications (Al-Saeedi 2001). Furthermore, Abuhussain et al. conducted a survey to evaluate the knowledge of diabetes in teachers with self-reported diabetes in Al Khubar, KSA. The study reported poor general knowledge of diabetes among teachers (Abahussain et al. 2005). Hence the findings of the study raise major concerns '*If well educated individuals with diabetes report poor knowledge, what about the general population?*'. Both studies reported poor knowledge of diabetes among people with diabetes who would have been exposed to some lifestyle modification throughout their treatment plan. Another study which was conducted in Jeddah, the second biggest city in Saudi Arabia, aimed to assess nutritional knowledge among 151 Saudi females. Participants were asked if they knew the food pyramid food groups and if they were able to list them. Only 39% of participants confirmed their knowledge of the food groups and were able to list them correctly (Bakhotmah 2012). Overall, it is a concern that Saudi females acquire poor dietary knowledge especially since they are responsible for the family meal preparation (Guy et al. 2009).

Sabra and colleagues have reported high levels of misconceptions about diabetes in 1030 Saudi adult primary health care attendees. Participants reported misconceptions in T2DM etiology, general concepts and diet. For instance, 44.9% of participants encouraged regular snacking while 38.2% believed that bitter food would reduce

elevated blood glucose levels. However, the results were not stratified by diabetes status, therefore it is difficult to predict the dietary knowledge among diabetics. In addition, the study was limited to male subjects and levels of knowledge were not assessed in females (Sabra et al. 2010).

Cultural and social factors are predictors of healthy lifestyle changes and adherence to such changes (Harris et al. 2007). One study evaluated cultural barriers to exercise and a healthy diet in 450 Saudi primary health care attendees in Riyadh, the capital city of Saudi Arabia (AlQuaiz et al. 2009). Lack of willpower (80.3%), lack of social support (72.4%) and lack of time (67.6%), lack of resources (60.2%) and lack of knowledge (46.3%) were all identified as barriers to healthy eating among participants. However, these findings cannot be extrapolated to a population with diabetes as the authors did not stratify barriers by diabetes status (AlQuaiz and Tayel 2009). Overall, it seems that the Saudi culture influences individual's dietary knowledge and behaviours. However, this area requires further investigation to better understand the barriers to healthy eating in order to develop culturally tailored prevention strategies and deliver better care and management (Nagelkerk et al. 2006).

In summary, Saudi studies suggest that the economic development has been paralleled by nutrition related health conditions. Interestingly, this increased income has not improved the populations nutritional knowledge or awareness (Bagchi 2008). The poor coordination of nutritional practice in Saudi Arabia and the lack of evidence based guidelines for nutritional therapy has been reported (Al Majwal et al. 2009). Given the current gap in nutritional evidence in Saudi Arabia, further studies are required to inform culturally tailored dietary awareness campaigns and to provide culturally specific health management in Saudi Arabia.

Summary

In this chapter, the local Saudi literature on the prevalence of T2DM, associated risk factors and gaps in the literature have been presented. In the next chapter (Chapter 4), the aims and objectives of this project are presented.

4 Aims and objectives

Introduction

The aim of this project is to evaluate the associations between dietary factors (anthropometric measures, selected food/beverage, and micronutrients) and the prevalence of type 2 diabetes mellitus (T2DM) in Saudi Arabian adults. In addition, this project aims to identify cultural barriers to healthy eating in this population to better understand the specific socio-cultural factors that may influence dietary behaviors.

4.2. Aims and objectives of this project

1. To conduct a systematic review on “Dietary factors and T2DM in Middle Eastern Adults”; this will allow identification of gaps in knowledge. Specifically, all observational (cohort, case-control and cross-sectional) and intervention studies which have assessed the association between dietary factors and T2DM in adult's ≥ 18 years living in the Middle Eastern region will be included.
2. To examine data from a large dataset ($n = 2631$) from a primary health care survey, collected for a multi-centre study in 2009 in Riyadh, Kingdom of Saudi Arabia (Biomarkers Screening in Riyadh Survey). This dataset will be used to examine the associations between nutritional factors and T2DM, specifically:

- a. Cross-sectional associations between anthropometric measurements and the prevalence of T2DM in Saudi adults.
 - b. Cross-sectional associations between macronutrient intake and the prevalence of T2DM in Saudi adults.
 - c. Cross-sectional associations between micronutrients and the prevalence of T2DM in Saudi adults.
3. To validate the food frequency questionnaire (FFQ) used in the Biomarkers Screening in Riyadh Survey (2009) against two 24 hour recalls.
 4. To identify cultural barriers to healthy eating in Saudi Arabia, specifically:
 - a. The development and piloting of a Cultural Barriers to Healthy Eating questionnaire (CBHE).
 - b. Using the CBHE questionnaire and two pre-existing questionnaires developed in Saudi Arabia and face to face interviews, to identify specific cultural barriers to healthy eating in Saudi adults with and without T2DM.

Summary

In this chapter, the aims and objectives of this project have been presented. In the next chapter (Chapter 5), the first aim of this project will be presented: a systematic review on “Dietary factors and type 2 diabetes in Middle Eastern Adults”.

5 Dietary factors and T2DM in the Middle East: what is the evidence for an association? – A systematic review

Introduction

In this chapter, the systematic review is presented, which includes the background, methods, results and discussion. The systematic review aimed to identify dietary factors associated with T2DM in the Middle Eastern adults and to identify gaps in the literature in this region.

5.1. Background

Diabetes mellitus is a global health burden affecting 285 million adults worldwide (6.4%) and costing the international health care system USD 367 billion (Zhang et al. 2010). It is also considered to be one of the most significant emerging public health problems in Middle Eastern countries. Global estimates have shown that the Middle East, as a whole, is ranked second in the world, among WHO regions, for the prevalence of diabetes, with an average prevalence of 9.3% (Shaw et al. 2010). Diabetes prevalence is projected to double over the next two decades in Middle Eastern countries (Boyle et al. 2010, Shaw et al. 2010).

The diet-diabetes relationship has received a great deal of scientific attention over the past decades, accompanied by methodological efforts to assess dietary intake accurately (Willett 1998). High caloric intake increases the risk of type 2 diabetes mellitus

(T2DM) by increasing body weight, thus decreasing insulin sensitivity (Parillo and Riccardi 2004). Refined carbohydrates, which are high in fructose, may increase the risk of T2DM by increasing insulin resistance (Gross et al. 2004). International evidence has identified some dietary items, such as whole-grain rich foods, cereal fibre, legumes, and green leafy vegetables which play a protective role against chronic conditions including T2DM (Carter et al. 2010, Sluijs et al. 2010, Sun et al. 2010). The nutritional composition (*i.e.*, fibre, vitamins and minerals) of protective foods may decrease the risk of T2DM by reducing inflammation, improving glucose metabolism, endothelial function, and insulin sensitivity (He et al. 2010).

The consumption of sugar sweetened beverages has shown a positive association with T2DM, this association is mediated by an increased body weight which disrupts glucose metabolism and insulin sensitivity (Wang et al. 2008, Hu and Malik 2010). Dietary energy density (DED) is correlated with T2DM by increasing body weight, and energy dense foods seem to increase glycaemic load and insulin resistance (Mendoza et al. 2007). Examining the diet as a whole in relation to health outcomes has complemented the traditional single nutrient assessment (Hu 2002). Studies have identified some protective dietary patterns against T2DM, such patterns are characterized by high intakes of vegetables, fruits, whole-grains and legumes (Fung et al. 2004, Brunner et al. 2008). Dietary patterns with high consumptions of processed meats, refined grains, sugar-sweetened beverages and fatty foods seem to increase the risk of diabetes (Schulze et al. 2005, Hodge et al. 2007).

It is well-established that lifestyle and dietary interventions play a major role in the prevention of T2DM both in the general population and high-risk individuals, but this evidence comes mostly from Western populations (Sartor et al. 1980, Eriksson et al.

1991, Rowley et al. 2000, Lindström et al. 2003, Uusitupa et al. 2011). Diet-related chronic conditions represent a major public health concern in the Middle East (Musaiger 2004, Al-Othaimen et al. 2007, Elhadd et al. 2007). The rapid urbanization and the fast economic boost imported the “Western diet” into the Middle East. The nutritional transition in the Middle East has introduced energy-dense, refined carbohydrates and fat-saturated cuisine (Musaiger and Al-Hazzaa 2012). This transition has paralleled the increase in lifestyle-related chronic conditions such as diabetes (Al-Shoshan 1992, Amuna and Zotor 2008). However, evidence linking these dietary habits to the emerging diabetes epidemic is not clearly defined in these settings (Nielsen 1999, Al Majwal et al. 2009, Ng et al. 2011, Amini et al. 2012). Therefore, we aimed to perform a systematic review of the literature to summarise the available evidence on the association between diet and the risk of T2DM in Middle Eastern countries, and to identify gaps for further research.

5.2. Materials and Methods

MEDLINE, CINAHL, Web of Science, and the Cochrane Library were searched from inception until May 2013. Reference lists of retrieved articles were scanned for further studies, and a registration of electronic email updates for relevant new published articles was performed. Grey literature was scrutinised (Saudi Bureau Library-UK) using electronic databases and hand searching of relevant theses. Authors, libraries (The British Library-UK, King Abdul-Aziz City of Science and Technology-KSA), and research centres (King Faisal Specialist Hospital & Research Centre in Jeddah and Riyadh-KSA, Bahrain Centre for Studies and Research) were contacted for further studies and unpublished literature.

No restrictions were made by language, publication status or year of publication. The search terms used included medical subject headings (MeSH) or the equivalent, and text word terms (*i.e.*, diet, diet records, nutrition/diet surveys, nutrition assessment, eating, food habits, AND Middle East AND type 2 diabetes mellitus). Middle Eastern countries were based on the MEDLINE list of countries. A specialist librarian was consulted for further search terms. Searches were tailored to individual databases.

Studies met the inclusion criteria if they fulfilled all of the following criteria:

Study design—randomised controlled trials, non-randomised intervention studies, cohort studies, case-control studies or cross-sectional studies;

Participants—all Middle Eastern adults (≥ 18 years of age) with the exception of those with type 1 diabetes;

Exposure/intervention—nutrition or dietary variables, including the quality/quantity of food intake, interventions aimed at dietary changes, food habits or dietary patterns measured via nutritional tools, or nutritional biomarkers; and

Outcome—incidence or prevalence of T2DM.

Following the database searching, titles and abstracts of articles were screened for potential relevance by one reviewer (LA). Studies not carried out in the Middle East, studies of children, and studies not measuring diabetes were excluded at this stage. Following this preliminary screening, full reports of potentially relevant studies were obtained, and two reviewers (LA, KR) independently assessed studies for

inclusion/exclusion using a checklist form based on the four inclusion criteria above. Where there was disagreement about the inclusion of a study, a third reviewer was consulted (SS).

Data were extracted from the included studies by two reviewers (LA, KR) independently using a predefined data abstraction form. Key data including details of the study design, participant characteristics, study setting, intervention/exposure (including assessment/validation, potential confounders), risk of bias (selection of participants, losses to follow up), and outcome assessment/method of diagnosis were extracted from each of the studies that met the inclusion criteria.

5.3. Results

Searching the electronic databases yielded 1662 references. Contacting authors, research centres, and searching the grey literature yielded an additional 69 references. Initial screening excluded 1643 articles (see Figure 5.1.), leaving 89 potentially relevant articles. Seven further studies were identified from scanning the reference lists of the 89 short-listed studies. In total, 96 studies went forward for formal inclusion/exclusion. Seventeen studies met the inclusion criteria, whilst the remaining 79 studies were excluded due to irrelevant study design, participants, exposure and outcome (see Figure 5.1.).

A narrative synthesis was chosen as the most appropriate method to analyse the data, as the included studies were heterogeneous. The included studies used different study designs and measured different exposures/interventions. Details of the included studies

are shown in Tables 5.1–5.3. A total of 17 studies met the inclusion criteria for this systematic review.

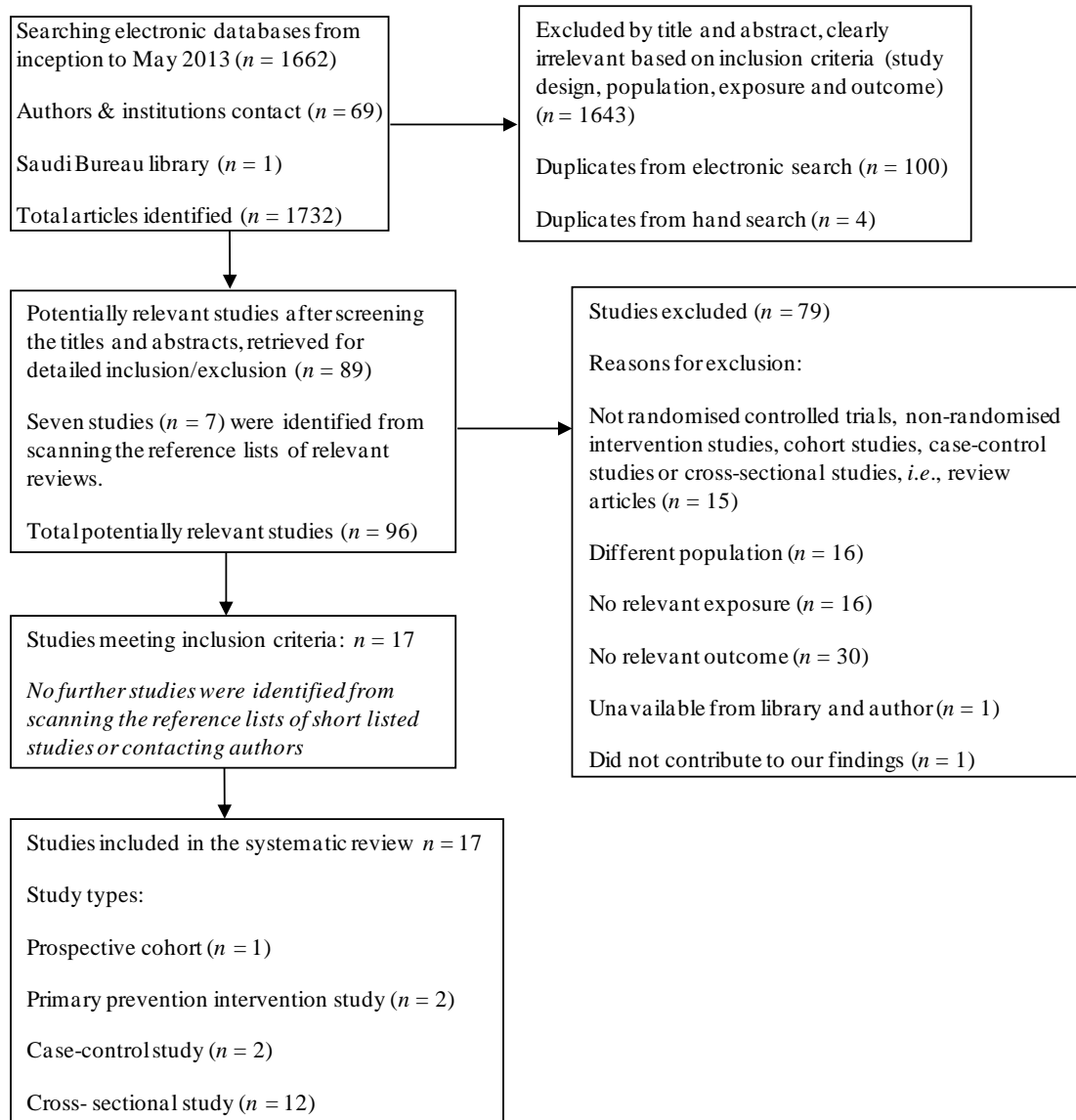


Figure 5.1. Flow diagram for the selection of studies

Table 5.1. Association of energy, nutrients, foods, and beverages with T2DM

Author	Study design	Country/study population	Sample size	Sex(%)	Age (years)	Dietary assessment method	Dietary factor	Results
Energy and nutrients								
Kahn <i>et al.</i> , 1971 (Kahn et al. 1971)	Prospective cohort. Follow-up: 2 years	Israeli civil-services employees	8369	M: 100	>40	Short dietary questionnaire	Total calories (kcal/day), total carbohydrate (g/day), animal protein (g/day), saturated fatty acid (g/day), and sugar calories (kcal/day).	There was no association between dietary variables assessed and T2DM incidence.
Foods								
Midhet <i>et al.</i> , 2010 (Midhet et al. 2010)	Case-control	Saudi Arabian PHCC's attendees	498	M: 48.6 F: 51.4	30–70	Food preference questions and 24-h DR	Food items consumed regularly, Kabsa (rice/chicken with rice), dates, fish, vegetables, bakery items, potato chips and/or French fries, snacks and hummus, full fat dairy products, coffee and/or tea with sugar, juices and soft drinks.	Routine consumption of Kabsa (OR 5.5, CI: 2.3–13.5), bakery items (OR 2.4, CI: 1.3–4.6), French fries (OR 2.2, CI: 1.2–3.9) and fish (OR 2.5, CI: 1.3–4.7) were associated with an increased risk of T2DM. Vegetables showed a protective effect (OR 0.4, CI: 0.2–0.7).
Ezmaillzadeh <i>et al.</i> , 2005 (Ezmaillzadeh et al. 2005)	Cross-sectional	Iranian residents	827	M: 43.2 F: 56.8	18–74	Validated 168-items FFQ (Willett format)	Whole- grain foods (e.g., dark breads, barley bread, popcorn, whole-grain breakfast cereal, wheat germ and bulgur). Refined grain foods (e.g., white breads,	The highest quartile of whole-grain consumption was associated with a reduced risk of T2DM (OR 0.88, CI: 0.8, 0.94) as compared to the reference

							iceberg bread, noodle, pasta, rice, toasted bread, milled barley, sweet bread, white flour, starch and biscuits).	category ($p < 0.05$). There was no significant increase in the risk of diabetes with refined-grain consumption (highest category OR 1.14, CI: 0.87–2.52)
Esmillzadeh <i>et al.</i> , 2011 (Esmillzadeh <i>et al.</i> 2011)	Cross-sectional	Iranian teachers	486	F: 100	≥ 40	Validated 168-items FFQ (Willet format)	Vegetable oil which included partially hydrogenated vegetable oil (PHVO) and non-hydrogenated vegetable oil (NHVO) (e.g., soyabean oil, olive oil, sunflower oil, maize oil, rapeseed oil).	No significant association was found between PHVO ($p = 0.31$) or NHVO ($p = 0.19$) and diabetes. However, diabetes prevalence increased across PHVO quintiles, and decreased across NHVO quintiles.
Khosravi-Boroujeni <i>et al.</i> , 2012 (Khosravi-Boroujeni <i>et al.</i> 2012)	Cross-sectional	Iranian residents	4774	M: 76 F: 24	> 19	Validated 49-items FFQ	Potato consumption.	There was a positive association ($p < 0.001$) between potato intake and risk of diabetes (OR 1.38, CI: 1.41–1.67).
Beverages								
Golozar <i>et al.</i> , 2011 (Golozar <i>et al.</i> 2011)	Cross-sectional	Iranian residents	50,039	M: 42.4 F: 57.6	≥ 30	Validated 158-items FFQ	Green and black tea consumption (mL/day).	Heavy green tea consumption (≥ 600 mL/day) was positively associated with T2DM (prevalence ratio

(PR) 1.24, CI: 1.05–1.47).								
Energy density								
Esmillzadeh <i>et al.</i> , 2012 (Esmailzadeh et al. 2012)	Cross- sectional	Iranian teachers	486	F: 100	≥40	Validated 168-items FFQ (Willet format)	Dietary energy density (DED) from food (kcal/g) ¹ .	No significant association between the highest quartile of DED _{Food} (prevalence ratio (PR): 1.06, CI: 0.42–2.73) and diabetes.
Kalter- Leibovici <i>et al.</i> , 2012 (Kalter- Leibovici et al. 2012)	Cross- sectional	Israel (Jewish and Arab residents)	1092	M: 49.6 F: 50.4	≥25	240-items FFQ	DED _{Food + Beverages} (kcal/g) ² .	Arabs with diabetes were more likely to be in the highest quartiles of DED (29.5% vs. 35.4%). The risk of diabetes was significantly higher in highest quartiles of DED (adjusted hazards ratio: 1.67, CI: 1.08–2.61) in comparison to lower quartiles (adjusted hazards ratio: 1.53, CI: 0.98–2.39).
FFQ indicates food frequency questionnaire; 24-h DR indicates twenty-four hour dietary recall; PHCC's indicates primary health care centres; T2DM indicates type 2 diabetes mellitus; PHVO indicates partially hydrogenated vegetable oil; NHVO indicates non-hydrogenated vegetable oil; ¹ DED was calculated by: energy intakes from foods (kcal/day)/total weight of foods consumed (g/day); ² DED was calculated by: total energy intake (kcal/day)/ total weight of food and drinks consumed (g/day).								

Table 5.2. Association between dietary patterns and T2DM

Author	Study design	Country/study population	Sample size	Sex (%)	Age (years)	Dietary assessment method	Dietary factor	Results
<i>A priori Dietary Patterns</i>								
Bilenko <i>et al.</i> , 2005 (Bilenko et al. 2005)	Cross-sectional	Israeli residents	1159	M: 44.9 F: 55.1	≥35	24-h DR	Mediterranean dietary score ¹ .	No significant difference was observed across Mediterranean diet score categories (low or high) and the prevalence of diabetes in both males and females.
Azadbakht <i>et al.</i> , 2006 (Azadbakht et al. 2006)	Cross-sectional	Iranian residents	581	M: 51 F: 49	≥18	Validated 168-items FFQ (Willet format)	Dietary diversity score (DDS) ² , which was from the five main food groups of the Food Guide Pyramid (bread/grains, fruits, vegetables, dairy, meat and meat substitutes). The five groups were divided into 23 (e.g., vegetables: vegetables, potatoes, tomatoes, starchy vegetables, legumes, yellow vegetables, green vegetables).	Although there was no protective effect of healthier diet score against diabetes, the risk of diabetes decreased significantly across quartiles of DDS ($p = 0.03$). Quartiles of DDS for whole-grains (OR-Q ₁ 1.45, CI: 1.09–1.88 vs. OR-Q ₃ 1.11, CI: 0.89–1.44), and vegetables (OR-Q ₁ 1.12, CI: 0.54–1.88 vs. OR-Q ₃ 1.05, CI: 0.89–1.34) did not have an inverse association with diabetes.
<i>A Posteriori Dietary Pattern</i>								
Naja <i>et al.</i> , 2012 (Naja et al. 2012)	Case-control	Lebanon (cases: Lebanese private clinic)	174	M: 60.3 F: 39.7	>18	97-items FFQ	4 dietary patterns, Refined Grains and Desserts (e.g., pasta, pizza, deserts), Traditional Lebanese	The Traditional Lebanese pattern showed significantly lower odds of T2DM (OR 0.46,

		attendees, controls: Lebanese residents)						(e.g., whole wheat bread, olives and olive oil), Fast Food (e.g., mixed nuts, French fries, and full fat milk), and Meat and Alcohol patterns (e.g., red meat, eggs, carbonated beverages).	CI: 0.22–0.97) while the Refined Grains (OR 3.85, CI: 1.31–11.23) and the Fast Food patterns (OR 2.80, CI: 1.41–5.59) significantly increased the odds of T2DM in Lebanese adults.
Esmillzadeh <i>et al.</i> , 2008 (Esmailzadeh et al. 2008)	Cross-sectional	Iranian teachers	486	F: 100	≥40	Validated 168-items FFQ (Willet format)		3 dietary patterns, Healthy (e.g., fruits, vegetables, legumes), Western (e.g., red meat, butter, pizza), and Iranian patterns (e.g., refined grains, potato, broth).	The prevalence of diabetes decreased significantly among quintiles of Healthy pattern ($p < 0.05$) and increased among quintiles of Western ($p < 0.05$) and Iranian patterns ($p = 0.24$). The Healthy pattern had a protective effect against diabetes (OR 0.29, CI: 0.11–1.07, $p = 0.07$).
Abu-Saad <i>et al.</i> , 2012 (Abu-Saad et al. 2012)	Cross-sectional	Israel (Jewish and Arab residents)	1104	M: 50 F: 50	≥25	240-items FFQ		4 dietary patterns, Ethnic (e.g., pita bread, olive oil and Arabic mixed meat), Healthy (e.g., fruits, low fat dairy products and whole grains), Fish and Meat Dishes (fish, meat and frying oil), Middle Eastern snacks and Fast Food patterns (e.g., savoury cheese, nuts, and fast food).	Scores for the Healthy and Ethnic pattern clearly differed by ethnicity. Hence, the two patterns were used for further analysis. The prevalence of diabetes was higher in increased tertiles of Ethnic pattern (T_3 20% vs. T_{1-2} 13%, $p = 0.001$), and participants with prevalent diabetes were more likely to be in the highest tertiles of Healthy pattern (T_3 25% vs. T_{1-2} 10%, $p < 0.001$). Arabs with prevalent diabetes were

								more likely to be in the highest tertiles of the healthy pattern (OR 5.00, CI: 2.92–8.55) in comparison to Jews with diabetes (OR 2.00, CI: 1.01–3.95).
Other Dietary Patterns								
Al Ali <i>et al.</i> , 2011 (Al Ali <i>et al.</i> 2011)	Cross-sectional	Syrian residents	1168	M: 47.7 F: 52.3	≥25	Frequency questionnaire	Healthy and unhealthy diets ³ .	Frequent fruit and vegetable consumption was associated with a reduced risk of T2DM (OR 0.70, CI: 0.48–1.03), but this did not reach statistical significance.
Alrabadi <i>et al.</i> , 2013 (Alrabadi 2013)	Cross-sectional	Jordanian residents	286	M: 49 F: 51	>40	Questionnaire	Vegetarianism ⁴ .	The prevalence of diabetes was significantly lower among vegetarians (38%) in comparison to non-vegetarians (44%).

24-h DR indicates twenty-four hour dietary recall; **FFQ** indicates food frequency questionnaire; ¹ **MD scores**: Reported foods ($n = 2200$) were categorized according to their dietary components (e.g., legumes, meat, vegetables and fruits) and points were given to the consumption of each group following Trichopoulou *et al.* methods (Trichopoulou *et al.* 1995). The lower the score (≤ 4) the lower the consumption of the Mediterranean diet. ² **DDS**: scores were based on the following: (servings/subgroups) $\times 2$. Scores were divided into quartiles and the higher the score the healthier the diet. ³ Diets were based on the frequency (days/week) of fruits and vegetables intake (< 3 or 3–6 or 7 days/week), lower frequencies (< 3) scored less (1 point), and higher frequencies (3–6, 7 days/week) scored more (2 and 3 points respectively). Participants with an unhealthy diet had lower tertiles for total scores. ⁴ **Vegetarianism**: A vegetarian diet was defined as meat and poultry intake < 1 time/month, while a non-vegetarian diet was defined as red meat or poultry intake ≥ 1 time/month.

Tables 5.3. Association between lifestyle factors and T2DM in intervention studies

Author	Study design	Country/study population	Sample size	Sex(%)	Age (years)	Follow-up (years)	Intervention	Results
Harati <i>et al.</i> , 2010 (Harati et al. 2010)	Primary prevention intervention study	Iranian residence	8212	M: 41 F: 59	>20	3.6	<p>Intervention:</p> <p>At baseline: intensive education to increase physical activity, reduce cigarette smoking, and face-to-face educational interviews to improve nutritional habits. The lifestyle modification intervention was based on guidelines recommendations by The American Heart Association and modified to suit the Iranian knowledge, attitude and practice that were assessed in a previous study (KAP study) (Azizi et al. 2009). Dieticians providing tailored nutrition interventions such as weight reduction diet, exchange list education, diet management, DASH diet, and ADA nutrition principles.</p> <p>For the next 2.6 years: nutritional classes (held for 4 days/week at clinics), group meetings, public sites, publications, public conferences, distribution of education materials and school-based programs were carried out.</p> <p>Control: Did not receive the intervention.</p>	<p>The lifestyle modification programme resulted in a statistically significant relative risk reduction of 65% in the incidence of diabetes (95% CI = 30%, 83%, $p = 0.003$).</p> <p>The incidence of diabetes was 8.2 per 1000 person-years in the intervention groups in comparison to 12.2 per 1000 person-years in the control group.</p>

Sarrafzadegan <i>et al.</i> , 2013 (Sarrafzadegan et al. 2013)	Primary prevention intervention study	Iranian residence	12,514 baseline (2001–2002)	M: 50	≥19	4	Intervention: interventions began at different times throughout the study and were at a community level using different approaches (e.g., mass media, health services).	The prevalence of diabetes did not decrease in the intervention group in both females (2001: 6.8%, 2007: 7.1%, $p = 0.38$) and males (2001: 5.8%, 2007: 7.1%, $p = 0.17$). However, there was a borderline significant increase in males of the reference group (2001: 4.0%, 2007: 5.7%, $p = 0.056$), and a non-significant increase in females of the reference group (2001: 5.8%, 2007: 7.3%, $p = 0.15$).
			9570 post-intervention (2007)	F: 50			Improve healthy eating, increase physical activity, reduce tobacco smoking and cope with stress. Additional secondary preventative measures were delivered to high-risk individuals (e.g., people with diabetes). Projects were tailored to meet participants needs (e.g., Healthy-lifestyles for High-risk Populations, Healthy Food for Healthy Communities, Isfahan Exercise Project, and Healthy Lifestyles for High-risk Populations).	
			Control: Did not receive the intervention.					

KAP study: Knowledge, Attitude and Practice study; **DASH** indicates Dietary approach to Stop Hypertension; **ADA** indicates American Diabetes Association.

Association of Energy, Nutrients, Foods, and Beverages with T2DM

In total, eight studies examined the association between energy, nutrients, different foods, and beverages and T2DM. For full details of the studies please refer to Table 5.1.

Energy and Nutrients

One prospective cohort study (Kahn et al. 1971) examined the association between total energy and some nutrients and the incidence of T2DM. Trained nurses assessed the frequency, amount and portion size of some food items (e.g., meat, poultry, fish, milk, beverages). The type and amount of fat consumed was assessed in more detail (e.g., what type of fat or oil was used in the preparation of food). The study reported no associations between the reported dietary items and the incidence of T2DM.

Foods

One case control study and 3 cross-sectional studies examined the association between different foods and the prevalence of T2DM. A case-control study conducted in Saudi Arabia (Midhet et al. 2010) measured the association between specific dietary items and the risk of T2DM. In 283 cases and 215 controls, results showed that routine consumption of certain foods such as Kabsa (OR 5.5, CI: 2.3–13.5), bakery items (OR 2.4, CI: 1.3–4.6), and French fries (OR 2.2, CI: 1.2–3.9) increased the risk of T2DM. Notably, fish consumption was associated with an increased risk of diabetes (OR 2.5, CI: 1.3–4.7). Routine consumption of vegetables showed a protective effect for the risk of T2DM (OR 0.4, CI: 0.2–0.7).

One cross-sectional study (Esmailzadeh et al. 2005) examined the association between whole and refined grains and T2DM. Participants reported higher intakes of refined grains rather than whole-grains. The highest quartile of whole-grain consumption was associated with a reduced risk of T2DM (OR 0.88, CI: 0.8–0.94) as compared to the reference category ($p < 0.05$), but there was no statistically significant trend over the four quartiles. There was no significant increase in the risk of diabetes with refined-grain consumption (highest category OR 1.14, CI: 0.87–2.52).

The second cross-sectional study (Khosravi-Boroujeni et al. 2012) examined the association between dietary potato intake (boiled form) and T2DM prevalence in Iranian adults. The results showed a positive association between the frequency of potato intake ($> \text{once/week}$) and T2DM (OR 1.38, CI: 1.14–1.67, $p < 0.001$).

The third cross-sectional study conducted in Iranian female teachers (Esmailzadeh and Azadbakht 2011) examined the correlation between vegetable oil consumption and T2DM prevalence. Women had a higher intake ($23 \pm 11 \text{ g/day}$) of partially hydrogenated vegetable oil (PHVO) in comparison to non-hydrogenated vegetable oil (NHVO) $22 \pm 10 \text{ g/day}$. The prevalence of diabetes increased among quintiles of PHVO, however, no significant associations were observed between diabetes and PHVO (OR: 2.11, CI: 0.55–9.47) or NHVO (OR: 0.51, CI: 0.10–1.51).

Beverages

A further cross-sectional study (Golozar et al. 2011) assessed the association between tea consumption and the prevalence of T2DM in Iranian adults. Heavy green tea

consumption (≥ 600 mL/day) was associated with T2DM (PR 1.24, CI: 1.05–1.47) while no significant association was observed for black tea (PR 1.02, CI: 0.94–1.12).

Energy Density

Two studies have examined energy density and T2DM. The first study (Esmailzadeh et al. 2012) observed the association between DED_{Food} and T2DM in Iranian women. Fasting plasma glucose increased among quartiles of DED_{Food} , however, no significant associations were observed between higher DED_{Food} and diabetes (PR: 1.06, CI: 0.42–2.73).

The second study (Kalter-Leibovici et al. 2012) assessed the association between $DED_{Food + Beverages}$ and T2DM in both Arabs and Jews. There was no significant association between $DED_{Food + Beverages}$ and diabetes ($p = 0.08$). However, participants with higher $DED_{Food + Beverages}$ (≥ 0.886) had a higher risk of diabetes (Adjusted hazard ratio: 1.67, CI: 1.08–2.61).

Association between Dietary Patterns and T2DM

In total, seven studies assessed different dietary patterns in relation to T2DM. For full details of the studies please refer to Table 5.2.

A Priori Dietary Patterns

The first study (Azadbakht et al. 2006) assessed the association between dietary diversity score (DDS) and T2DM in Iranian adults. Trained dieticians assessed dietary

intake. The results showed that the probability of having diabetes decreased among increasing quartiles of DDS ($p = 0.03$). A decrease of diabetes probability was observed among quartiles of whole grains DDS (OR-Q₁ 1.45, CI: 1.09–1.88 vs. OR-Q₃ 1.11, CI: 0.89–1.44). However, there was no observed protective effect vegetables DDS (OR_{vegetables} 1.05, CI: 0.89–1.34).

The second study (Bilenko et al. 2005) examined the association between the Mediterranean diet score (MD) and the prevalence of T2DM. Reported food groups were given a score (≤ 4 = low MD or ≥ 5 = high MD) to categorise the intake of the Mediterranean diet. The results showed no statistical differences for the prevalence of diabetes across high or low consumers of the MD. The prevalence of diabetes in males with low consumption of the MD was 12.7% while high consumers had a prevalence of 11.0%. A similar trend was found in females (13.6% vs. 9.3% respectively).

A Posteriori Dietary Patterns

A case-control study conducted in Lebanon (Naja et al. 2012) measured the association between diet and T2DM. Dietary intake was assessed in one to one interviews using a FFQ which represented the Lebanese diet. Principal component factor analysis (PCA) identified four dietary patterns, Refined Grains and Dessert, Traditional Lebanese, Fast Food, and Meat and Alcohol patterns. In 58 newly diagnosed cases of T2DM and 116 controls, results showed that Refined Grains and Desserts (OR 3.85, CI: 1.31–11.23), and Fast Food (OR 2.80, CI: 1.41–5.59) patterns significantly increased the risk of T2DM. Conversely, the Traditional Lebanese pattern had a protective effect (OR 0.46, CI: 0.22–0.97). No association was observed between the Meat and Alcohol pattern and T2DM (OR 1.43, CI: 0.83–2.46).

A cross-sectional study (Esmailzadeh and Azadbakht 2008) including female teachers from Tehran in Iran examined dietary patterns in relation to T2DM prevalence. PCA identified three dietary patterns, Western, Healthy and Iranian. The prevalence of diabetes decreased among quintiles of the Healthy pattern ($p < 0.05$) and increased among quintiles of the Western pattern ($p < 0.05$). There were no significant associations between the prevalence of T2DM and quintiles of the Iranian pattern ($p = 0.24$). The Healthy pattern had a borderline significant protective effect against diabetes (OR 0.29, CI: 0.11–1.07, $p = 0.07$), whilst no significant associations were observed for the Western and Iranian dietary patterns (OR 3.42, CI: 0.88–13.31, OR 2.11, CI: 0.66–7.12 respectively).

A further study (Abu-Saad et al. 2012) assessed the association between dietary patterns and T2DM. PCA identified four dietary patterns, Ethnic, Healthy, Fish and Meat, Middle Eastern snacks and fast food patterns. Participants with diabetes had a healthier diet, they were more likely to be in higher tertiles of the Healthy pattern (T_{1-2} 10% vs. T_3 25%, $p < 0.001$). Arabs with diabetes were more likely to be in higher tertiles of the Healthy pattern in comparison to Jews (OR: 5.00, CI: 2.92–8.55 and OR: 2.00, CI: 1.01–3.95 respectively).

Other Dietary Patterns

A cross-sectional study (Al Ali et al. 2011) examined the association between unhealthy diet scores and the prevalence of T2DM in Syrian adults. The questionnaire used assessed the frequency of fruit and vegetable consumption. Results showed that having

an unhealthy diet (lower frequencies of fruits and vegetables consumption) did not show a significant protective effect against T2DM (OR 0.70, CI: 0.48–1.03).

A cross-sectional study (Alrabadi 2013) assessed the association between vegetarianism and the prevalence of diabetes in Jordanian adults. Participants were required to complete a questionnaire to report whether they were vegetarians or non-vegetarians. Diabetes prevalence was significantly higher ($p < 0.05$) among non-vegetarians (44%) in comparison to vegetarians (38% reported diabetes).

Association between Lifestyle Factors and T2DM

In total, two non-randomised primary prevention studies examined the effect of lifestyle interventions on T2DM in Iranian adults. For full details of the studies please refer to Table 5.3.

The first study (Harati et al. 2010) assessed the effectiveness of a multi-factorial intervention on the incidence of T2DM in the community. One cluster (from one health centre, $n = 3098$) received the intervention, whilst two clusters (from two health centres, $n = 5114$) acted as the control group. The incidence of diabetes was 12.2 per 1000 person-years in the control group, and 8.2 per 1000 person-years following the intervention, with a relative risk reduction of 65% (95% CI = 30%–83%, $p = 0.003$). The attributable risk reduction (ARR) was 0.39% and the number needed to treat (NNT) was 256 to prevent one case of diabetes in the whole population.

The other intervention study (Sarrafzadegan et al. 2013) examined the effect of comprehensive lifestyle modification in Iranian adults over several years. The baseline

sample (years 2000–2001) included 6175 participants in the intervention group and 6339 participants in the control group. Post lifestyle modification (year 2007) included 4179 participants in the intervention group whilst the control group included 4853 participants. The baseline prevalence of diabetes in the intervention area was 6.8% in females and 5.8% in males. The comprehensive lifestyle program did not reduce the prevalence of diabetes in the intervention area (7.1% in females and 7.1% in males). However, the prevalence of diabetes in the reference area increased by 25.9% in females and 42.5% in males.

5.4. Methodological Quality of Included Studies

The assessment of the methodological quality of the included studies (all non-randomised) was informed by guidelines from the Cochrane Handbook (Higgins et al. 2009). The methodological quality of the prospective cohort study (Kahn et al. 1971) and the case-control studies (Midhet et al. 2010, Naja et al. 2012) were assessed using the Newcastle-Ottawa Quality Assessment Scale (Wells et al.). Results are presented in Table 5.4.

Table 5.4. Methodological quality of the cohort study and case-control studies

Cohort Study	Selection	Comparability	Outcome
Kahn et al. 1971	**	*	*
Case-control Study	Selection	Comparability	Exposure
Midhet et al. 2010	****	**	*
Naja et al. 2012	****	**	**

The Newcastle-Ottawa Assessment Scale (Wells et al.) for the cohort studies—a study can be awarded a maximum of one star for each category of selection (representative of the exposed cohort,

selection of the non-exposed cohort, ascertainment of exposure), and outcome categories (assessment of outcome, sufficient follow-up for outcome to occur, adequacy of cohorts follow up). A maximum of 2 stars can be awarded for comparability (controls for important factors, controls for additional factors). Case-control studies—a study can be awarded a maximum of 4 stars for selection (case definition, representativeness of the cases, control selection and definition of the controls), a maximum of 2 stars for comparability (cases and controls must be matched for in the design of analysis) and a maximum of 4 stars for exposure (three questions assessing ascertainment of the exposure, the same method of ascertainment of exposure in cases and controls, and the non-response rate).

The prospective cohort study (Kahn et al. 1971) included male-civil service employees working in three different cities in Israel so they were a selected group and not truly representative of the Israeli population. Trained nurses administered the dietary questionnaire and models of foods were used to estimate portion size. More emphasis was given to the type and amount of fat consumed, which may have introduced some bias. Participants with diabetes or abnormal glucose levels were excluded from the recruitment. The association between dietary variables and diabetes were not clearly presented in this study, however, analysis was stratified by age groups and place of birth so this study scored one of a possible two stars for comparability. The assessment of diabetes was unclear and losses to follow up were not described, but the follow up period of two years was sufficient as 131 incident cases of T2DM were identified, hence one star was awarded for the outcome.

In the case-control study by Midhet and colleagues (Midhet et al. 2010), cases were known to the primary health care centres (PHCC's), and controls were selected on the basis of an absence of diabetes (blood glucose level of ≤ 180 mg/100 mL) from the same population. Every fifth patient visiting the PHCC's was asked to participate in the study. The authors state that the cases and controls were not matched, but potential confounders (including age, sex, and family history of diabetes) were controlled for in the analysis. Interviewers were not blinded to cases or controls, and cases were asked more questions on their dietary habits prior to the diagnosis of T2DM, which may

increase the likelihood of assessor's bias and recall bias. The exposure was specific food items, with no justification by the authors for the chosen foods, and the nutritional composition of foods was not examined in this study. The authors state that some participants with incomplete data were excluded from the analysis, but the numbers were not provided separately for the cases and controls.

The case-control study by Naja and colleagues (Naja et al. 2012) included cases that were newly diagnosed with T2DM (within six months) attending private Clinics or the Dietary Department at the American University of Beirut Medical Centre. Healthy controls (free of self-reported diabetes) were from the general population living in the same residential area as the cases. Two stars were awarded for comparability; two controls were selected to match each case, by age, sex and residential area. The FFQ was not validated, and the interviewers were not blinded to cases or controls. Cases were asked to report dietary intake one year before diabetes diagnosis while controls were asked to report for the previous year. The foods assessed by the questionnaire were clearly mentioned and nutritional analysis was clearly described. The response rate of cases was 89% and 82% for controls.

The methodological quality of the primary prevention intervention studies (Harati et al. 2010, Sarrafzadegan et al. 2013) was assessed using the Cochrane risk of bias tool (Higgins and Altman 2009). This tool examines six domains, namely: sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective outcome reporting and other sources of bias. Neither of the two intervention studies were randomised so the first two domains of the risk of bias tool are not relevant here. The study by Harati and colleagues (Harati et al. 2010) had a clustered design whereby one medical centre (of a total of 20 enrolled

in a large prospective study) received the intervention, and two acted as the comparison group. Blinding of lifestyle interventions is problematic, but this was addressed to some degree in the cluster design. The primary outcome was incidence of T2DM, which was clearly defined. Possible confounding variables were adjusted for in the analysis, and clustering was taken into consideration by the use of a random effects model. The loss to follow-up was high at 40%, but this was comparable between intervention and comparison groups.

The Sarrafzadegan et al. study (Sarrafzadegan et al. 2013) had a clustered design where two districts served as the intervention group, and one district served as the control. Diabetes was one of the cardiometabolic risk factors assessed in the study, and a diagnosis of diabetes was confirmed if FPG \geq 126 mg/dL or the intake of diabetes medications. The outcomes of the study were examined in two cross-sectional surveys, one in 2000 – 2001 (baseline) and one in 2007 (post intervention) and participants were selected using multistage random sampling.

The methodological quality of the cross-sectional studies (Esmailzadeh et al. 2005, Azadbakht et al. 2006, Esmailzadeh and Azadbakht 2008, Al Ali et al. 2011, Esmailzadeh and Azadbakht 2011, Esmailzadeh et al. 2012, Khosravi-Boroujeni et al. 2012, Alrabadi 2013) was assessed by means of choice of population, sampling method, exposure, and outcome measurement. The population of two studies (Esmailzadeh et al. 2005, Azadbakht et al. 2006) were a subsample of a larger prospective study (TLGS) which included 15,005 participants from different age groups and sexes living in Tehran. The authors state that the participants were randomly selected. Dietary intake was assessed using a validated FFQ (against twelve 24-h dietary recalls and biomarkers) to measure participant's intake of whole-grain and refined grain, and to assess the

dietary diversity score (DDS). Dieticians completed the FFQ. The foods assessed were clearly defined, as were the methods of DDS calculation. Outcome measures were robust and clearly defined ($\text{FPG} \geq 126 \text{ mg/dL}$ or $2 \text{ OGTT} \geq 200 \text{ mg/dL}$).

Three cross-sectional studies by Esmailzadeh et al. (Esmailzadeh and Azadbakht 2008, Esmailzadeh and Azadbakht 2011, Esmailzadeh et al. 2012) were conducted in the same population but reported different dietary exposures. The population studied was limited to female teachers working in Tehran, Iran. The authors used multistage cluster random sampling method, where they divided the 20 districts of Tehran Educational Offices into four areas (northern, southern, western, and eastern). One district from each area was randomly selected, followed by a random selection of schools (private and public) and number of teachers for each district. The dietary assessment tool (FFQ) was validated against twelve 24-h dietary recalls and recovery biomarkers. The FFQ was used to look at different dietary factors, vegetable oils, DED_{Food} , and dietary patterns in relation to diabetes. The two vegetable oils assessed in the study (PHVO and NHVO) were clearly defined. The methods of DED_{Food} calculations were clearly defined by the authors. Although the authors calculated DED from food only, they did not adjust for energy intake from beverages. The authors clearly stated the food grouping method used for dietary patterns that was based on nutrients similarity. The labelling of each identified pattern and the foods included were clearly mentioned in the study. Diabetes diagnosis was well defined ($\text{FPG} \geq 6.93 \text{ mmol/L}$).

The study by Khosravi-Boroujeni and colleagues (Khosravi-Boroujeni et al. 2012) included a sub-sample Isfahan Healthy Heart Programme-2003 ($n = 12,514$). Multistage random-cluster sampling method was used. Trained technicians completed a FFQ to assess potato intake. The authors state that the FFQ was validated, however, methods of

validation were not clearly stated. The outcome was clearly defined (FPG > 126 mg/dL or 2-h postprandial > 200 mg/dL or use of diabetes drugs).

The population of the Golozar et al. study (Golozar et al. 2011) is part of the Golestan Cohort Study ($n = 50,044$) which included both sexes from different age groups. Systematic clustering based on household numbers was used to randomly recruit 39,399 residents in the Golestan Province. The remaining participants, in rural areas, were contacted through the primary health care centres in villages. Trained dieticians administered a FFQ to assess tea intake. The questionnaire was validated against twelve 24-h recalls in 131 individuals. The authors did not justify the choice of dietary variables. Diabetes was self-reported.

Two cross-sectional studies from Israel (Abu-Saad et al. 2012, Kalter-Leibovici et al. 2012) included a random population-based sample from Hedra district. A random sample was selected from the population registry and was equally stratified by sex and ethnicity. The sample had similar socio-demographic characteristics. Personal interviews were carried out using a 2-step quantified FFQ. The FFQ was developed for Jewish people and modified for Arabs. However, the questionnaire was not validated. $DED_{\text{Food} + \text{Beverage}}$ and dietary patterns were assessed. DED calculation was clearly defined, however, caloric consumption reports of 6000 kcal/day were included in the analysis, and it is possible that outliers and over-reporters increased the distribution of the data and affected the overall dietary results. The labelling of each dietary pattern and the foods included were clearly mentioned. The food items were grouped based on similarity of common usage, ethnic origin and nutrient composition. Potential confounders were clearly adjusted for in the analysis. Diabetes was self-reported.

The cross-sectional study by Bilenko et al. was part of the Negev Nutrition Study in Israel (Bilenko et al. 2005). A random proportional geographic cluster sample of the Negev residence was selected, and a random adult of each household was chosen to participate in the study. A single modified multi-pass 24-h questionnaire, which was adapted from the United States Department of Agriculture, was used to collect dietary information. Although a single recall cannot represent usual intake, the multi-pass method provides a structured and staged interview that allows the participant to recall dietary information. The Mediterranean scoring methods were clearly defined. Diabetes was not the main outcome in the study and possible confounders were not adjusted for in the analysis. Outcome measures were clear in the study.

The household survey by Al Ali et al. (Al Ali et al. 2011) was part of the 2nd Aleppo Household Survey conducted in 2006. Two-stage cluster sampling method was used, 27 neighbourhoods were randomly selected, followed by a random selection of 1268 households, and a random adult (≥ 25 years) from each household was invited to participate. Interviewers administered a questionnaire which assessed the frequency of fruit and vegetable intake. Dietary methods indicate that the frequency categories of fruits and vegetables were based on arbitrary decisions. Diabetes diagnoses was based on self-reports and $\text{FPG} \geq 126 \text{ mg/dL}$.

The cross-sectional study (Alrabadi 2013) conducted in Ajloun, Jordan did not report the questionnaire distribution, population choice, and sampling methods. The authors did not justify the categorization of vegetarians (*i.e.*, what guidelines they followed, as some participants labelled as vegetarians ate meat but infrequently). Participants completed the questionnaires, and diabetes was self-reported.

5.5. Discussion

Extensive searching including electronic databases, hand searching of relevant theses, libraries, research centres, and contacting authors in the field, identified relatively few studies reporting an association between dietary factors and the risk of T2DM in Middle Eastern adults. Seventeen studies met the inclusion criteria, one prospective cohort (Kahn et al. 1971), two primary prevention intervention studies (Harati et al. 2010, Sarrafzadegan et al. 2013), two case-control (Midhet et al. 2010), and 12 cross-sectional studies (Bilenko et al. 2005, Esmailzadeh et al. 2005, Azadbakht et al. 2006, Esmailzadeh and Azadbakht 2008, Al Ali et al. 2011, Esmailzadeh and Azadbakht 2011, Golozar et al. 2011, Esmailzadeh et al. 2012, Kaler-Leibovici et al. 2012, Khosravi-Boroujeni et al. 2012, Alrabadi 2013). Although some of the included studies assessed similar nutritional exposures, they were of different methodology and study design.

One of the very few cohort studies in the Middle Eastern area found no association between total energy and nutrient intake and the incidence of T2DM in men (Kahn et al. 1971). Nutritional evidence provides controversial findings on the associations between dietary macronutrients and diabetes (Alhazmi et al. 2012). However, large cohort studies have highlighted the effect of types of dietary fat (van Dam et al. 2002), protein (Sluijs et al. 2010), and carbohydrates (Fung et al. 2002) on the risk of T2DM. Esmailzadeh and colleagues (Esmailzadeh et al. 2005) reported an inverse association between whole-grain consumption and the risk of diabetes. These findings do parallel results of observational studies from US populations (McKeown et al. 2002, de Munter et al. 2007). For example, the Framingham Offspring Study found that whole-grain consumption improved metabolic markers in 3481 participants, thus reducing the risk of

T2DM (McKeown et al. 2002). Similarly, the Nurses' Health Studies (NHSs) I and II found that whole-grain intake had a protective role against T2DM (de Munter et al. 2007).

In this review, two studies reported an association between increased potato consumption and risk of T2DM (Midhet et al. 2010, Khosravi-Boroujeni et al. 2012). The effect of residual confounding is possible when examining single foods, and adjustment for confounding and dietary variables should be carefully considered. Nevertheless, these results are consistent with findings from Western countries (Halton et al. 2006, Esposito et al. 2011) and warrant further investigation in Middle Eastern populations. For instance, a prospective study which examined the association between potato and french fries consumption and T2DM from the Nurses' Health Study (NHSs) found a correlation between higher intake of potato products and the risk of T2DM (Halton et al. 2006). Although the case-control study (Midhet et al. 2010) suggested an association between fish consumption and the risk of diabetes, this may be attributed to the cooking style of fish in Saudi Arabia, as fish is usually deep fried and accompanied by either fried rice or bread and a fat dense sauce. Midhet et al. also highlighted the protective effect of increased vegetable consumption. A recent meta analysis found that green leafy vegetables significantly decrease the risk of T2DM, whilst other vegetables have a modest protective effect (Esposito and Giugliano 2011).

Two recent cross-sectional studies (Esmailzadeh and Azadbakht 2011, Alrabadi 2013) included in this review found that reduced intakes of animal protein and the use of NHVO are associated with a lower prevalence of T2DM in Middle Eastern adults. Despite the cross-sectional design, these findings are consistent with reports from other regions of the world. For example, the Adventist Health Study-2, which included

60,903 participants, found that semi-vegetarians had a lower risk of diabetes (Tonstad et al. 2009), and the Nurses' Health Study reported an inverse association between vegetable fat and T2DM in women (Colditz et al. 1992).

Observational evidence demonstrates mixed results on the association between DED and health outcomes (Johnson et al. 2009). However, nutritional studies have suggested that DED is associated with a higher risk of diabetes (Wang et al. 2008) and diabetes markers (Mendoza et al. 2007, Esmailzadeh et al. 2011). Two cross-sectional studies (Esmailzadeh et al. 2012, Kalter-Leibovici et al. 2012) in this review have examined the association between DED and T2DM, but the investigators used different methods to calculate DED. Although it has recently been suggested that calculating DED from food only is a better method to identify dietary risk factors for obesity (Perez-Escamilla et al. 2012), DED_{Food} failed to show an association, whilst $DED_{Food + Beverages}$ seems to be associated with a higher risk of diabetes. The main limitation was the use of the FFQ as it largely underestimates caloric intake, and showed low correlations with energy biomarkers (Schatzkin et al. 2003). The results should be interpreted cautiously given the methodological limitations.

Although dietary patterns analysis lacks stability and includes some arbitrary decisions such as food grouping, this approach provides new insights of the diet-disease relationship as it examines the diet as whole (Hu 2002, Moeller et al. 2007). This method has showed promising results in identifying dietary patterns associated with chronic conditions (Baxter et al. 2006, Lutsey et al. 2008). The lack of consistent associations between selected dietary patterns and T2DM in some of the included studies may be attributed to the lack of stability of dietary patterns, cross-sectional design and methodological limitations of the studies. Higher DDS (Azadbakht et al.

2006), MD scores (Bilenko et al. 2005) and traditional Lebanese dietary patterns, which share similar aspects of the Mediterranean diet, seem to have a protective role against diabetes (Naja et al. 2012), which is in agreement with international evidence (Martinez-Gonzalez et al. 2008, Kastorini et al. 2009).

The intervention studies (Harati et al. 2010, Sarrafzadegan et al. 2013) included a limited number of clusters and data were reported at the individual level. The interventions were multi-factorial, so it is not possible to tease out the effects of dietary modifications alone. Nevertheless, the results show that at a population level such interventions are feasible, and whilst taking into account the methodological limitations, the results are promising, and in line with international evidence (Lindström et al. 2003, Kosaka et al. 2005, Ramachandran et al. 2006, Lindström et al. 2008, Knowler et al. 2009).

There are several limitations of the data included in this review that should be considered. The applicability of findings from the included studies, which originate from a few countries in the Middle East, to other Middle Eastern populations is questionable, because dietary habits do vary across Middle Eastern countries (Al-Shahri 2002, Zhang et al. 2010). Hence, there is a need for additional studies to be conducted, which might detect specific dietary factors associated with the risk of diabetes across different populations in the Middle East. The included studies were also of variable methodological quality. Data from cross-sectional analyses cannot infer causality, but can only describe associations between dietary variables and the prevalence of diabetes. Failing to control for confounding variables (*i.e.*, energy intake), and reverse-causation might undermine the validity of findings in some of the included studies. This could

explain, for example, the paradoxical associations of green tea consumption with T2DM as reported in one of the included studies (Golozar et al. 2011).

The FFQ is an inexpensive tool and easy to administer, it is widely used in nutritional epidemiological studies (Willett et al. 2007). However, this nutritional tool is prone to the risk of recall bias (Khani et al. 2004), measurement error, and inaccuracy in assessing dietary intake. Nevertheless, in order to report accurate data, the validation of the FFQ is essential (Willett 1998). Only seven studies administered a validated FFQ, whilst two studies assessed diet using a 24-h dietary recall. The interpretation of results of the other seven studies is problematic, as some used non-validated tools and others administered questionnaires of poor structure and design.

T2DM is a growing public health problem in the Middle East (Hossain et al. 2007). Nutritional evidence recommends modifying diet composition to prevent T2DM (Hu et al. 2001, Willett et al. 2002). Large-scale randomised trials have demonstrated that multifaceted lifestyle interventions, including dietary modification, represents an effective strategy in the prevention of T2DM especially in high-risk individuals (Sartor et al. 1980, Eriksson and Lindgärde 1991, Lindström et al. 2003, Uusitupa et al. 2011) (Knowler et al. 2002, Kosaka et al. 2005, Ramachandran et al. 2006, Li et al. 2008, Knowler et al. 2009), however this has not been confirmed in Middle Eastern populations. The evidence to date from the Middle East highlights the urgent need for well-designed dietary interventions, as very few studies have quantified the nutritional problem accurately (Nielsen 1999, Al Majwal et al. 2009, Mehio Sibai et al. 2010). Lack of validated nutritional tools across countries in the Middle East and the difficulty in assessing and reporting dietary intake accurately are possible factors for the scant body of nutritional evidence in the Middle East.

5.6. Conclusions

Despite extensive searching, relatively few studies met the inclusion criteria for this systematic review examining the association between dietary factors and risk of T2DM in Middle Eastern populations. Eating habits are obviously heterogeneous across different populations in the Middle East; nevertheless, they are likely to play an important role in the emerging epidemics of diabetes and obesity, or in other words, the “diabesity epidemic” (Astrup et al. 2000) in the Middle East. Currently, the available data are not sufficient to identify specific dietary components associated with the risk of T2DM in these populations, and well-designed nutritional studies are needed.

Summary

In this chapter, the systematic review on dietary factors and T2DM in the Middle East has been presented. The review highlighted the gaps in dietary research in this area, specifically, in Saudi Arabia where only one study originated. In the next chapter (Chapter 6), the survey methods of the Biomarkers Screening in Riyadh Survey (2009) will be presented.

6 The biomarkers screening in Riyadh (2009) survey methods

Introduction

In this chapter, the Biomarkers Screening in Riyadh (BSR) survey (2009) is described, and the aspects of the methods used in survey are presented.

6.1. Biomarkers Research Program

In brief, the Biomarkers Research Program was launched in 2009 in the urban area of Riyadh, Saudi Arabia, to collect, identify and screen novel biomarkers for chronic non-communicable diseases such as diabetes mellitus and cardiovascular disease amongst consenting Saudis aged ≥ 6 years. Participants were recruited from different primary health care centres (PHCC's) across Riyadh city. The program is led by investigators at the Biomarkers Research Centre of King Saud University in Riyadh, and the Ministry of Health in Saudi Arabia. The research centre works in close collaboration with 150 PHCC's in the central region of Saudi Arabia (BRP 2010).

One of the collaborative efforts between the Biomarkers Research Program and the Ministry of Health in Riyadh, KSA is the Biomarkers Screening in Riyadh survey. The Biomarkers Screening in Riyadh survey, part of the wider Biomarkers Research Program, was launched to identify novel biomarkers of chronic non-communicable diseases. More than 14,000 consenting participants joined the survey and completed a questionnaire (available in Appendix 1) and a sub-sample ($n = 3248$) completed a food

frequency questionnaire (FFQ) (available in Appendix 2). Blood samples were collected from participants and stored in the Biomarkers Research Program bio-bank. A number of scientific outputs have been produced from the Biomarkers Screening in Riyadh survey (Al-Daghri 2010, AL-Daghri et al. 2010, Al-Daghri et al. 2010, Al-Daghri et al. 2010, Al-Daghri et al. 2011, Al-Daghri et al. 2011).

6.2. Collaboration

Professor Sudhesh Kumar from Warwick Medical School has established an ongoing collaboration with the Biomarkers Screening Survey in Riyadh, Saudi Arabia (Kumar 2010). The supervisors of this current project and the research centre in Riyadh signed an agreement (available in Appendix 3), and provided an electronic dataset of a subsample of the Biomarkers Screening Survey (2009) ($n = 3248$) including those individuals who completed the FFQ.

Inclusion criteria

1. Females and males aged ≥ 18 years.
2. Completed the demographic questionnaire.
3. Completed the FFQ questionnaire.

Exclusion criteria

1. Younger than 18 years of age.
2. Type 1 diabetes mellitus.
3. Current gestational diabetes.
4. Did not complete the FFQ.
5. Did not complete the demographic questionnaire.

6.3. The Biomarkers Screening in Riyadh Survey (2009) study design

The survey was carried out using a randomised cross-sectional design.

6.4. The Biomarkers Screening in Riyadh Survey (2009) study setting

The multi- centre study was conducted in 2009 and took place in 150 PHHC's in Riyadh, Saudi Arabia.

6.5. Ethical approval for the Biomarkers Screening in Riyadh Survey (2009)

Ethical approval was obtained from the Ethics Committee of the College of Medicine Research Centre, King Saud University, Riyadh, KSA (available in Appendix 4).

6.6. Participant selection of the Biomarkers Screening in Riyadh Survey (2009)

A total of 14060 Saudis aged ≥ 6 years old were randomly selected from the roster of 150 PHCC's of Riyadh city. For each PHCC, a physician invited participants from randomly selected households (alternate houses). The number of subjects collected from each PHCC was dependent on the total population assigned to the respective PHCC.

6.7. Data collection of the Biomarkers Screening in Riyadh Survey (2009)

Consenting participants were requested to arrive at their local PHCC's in an overnight fasting state. Physicians and trained research nurses collected socio-demographic, anthropometric, dietary, and biochemical data.

6.8. Socio-demographic measurements and medical history

Physicians and research nurses completed a questionnaire (available in Appendix 1) which assessed age, sex, marital status, consanguinity, occupation, annual income, education level, medical family history (diabetes, hypertension, hyperlipidemia, obesity, coronary heart disease, cancer, asthma and other diseases), participants medical history (diabetes, hypertension, renal disease, liver disease, dyslipidemia, coronary heart disease, cancer, asthma and other diseases) and smoking habits (cigarette smoker, shisha smoker, ex-smoker, non-smoker, number of packs/shisha per day, duration of smoking/quitting).

6.9. Anthropometric measurements

Trained research nurses recorded anthropometric measurements. Measurements included body weight (kg), height (cm), waist circumference (cm), hip circumference (cm), and sagittal abdominal diameter (cm). Body weight was measured to the nearest 0.1 kg using a Standardized Detecto Balance Beam scale, with participants wearing light clothing. A Standardized Stadiometer was used for height measurements.

Participants were required to stand upright on a flat surface with no shoes on and the back of their heels on the Stadiometer, height was measured to the nearest 0.5 cm. Waist and hip circumference was measured using a standardized measuring tape to the nearest centimeter. Participants were required to stand upright, feet together, arms to the side and relax their abdomen. Waist circumference measurements were taken midway between the lowest rib and iliac crest. Female's hip measurements were taken at the level of greater trochanters, whilst male's measurements were taken 2-3 inches below the navel.

The research nurse measured the sagittal abdominal diameter (cm) using an abdominal caliper. Participants were in a supine position, and were requested to bend their knees to a 45° angle and to keep their feet flat on the examination table. Sagittal abdominal diameter was recorded as the distance between the blades of the caliper at the end of normal expiration. Body mass index (BMI) was calculated to define overweight and obesity; weight (kg) divided by height (m²) in squared meters (WHO 2004).

6.10. Dietary measurements

Dietary intake was assessed using a semi quantitative food frequency questionnaire (FFQ) which was specifically developed for the survey (available in Appendix 2). The FFQ was completed by physicians, and trained research nurses. The FFQ measured the intake (quantity) of various food groups on a daily, weekly and monthly basis. The type and quantity of food groups were assessed. The type of dietary intake was assessed on the basis of fat content, sugar intake, type of food (e.g. grains), and cooking methods. Portion size was reported as grams, litres, and servings (e.g. cups, teaspoons, pieces). The included food groups in the FFQ were bread (e.g. white bread, brown bread),

cereals (e.g. corn flakes, bran flakes, porridge), meat (e.g. beef, sausage, kebab), seafood (e.g. white fish, canned fish, shrimps), vegetables (e.g. potatoes, peas, green leafy vegetables), fruits (e.g. apples, watermelon, canned fruits), traditional meals (e.g. gereesh, humus, falafel), fast food meals (e.g. pizza, burgers), bakery items (e.g. biscuits, sweets, cake), eggs and dairy products (e.g. eggs, milk, yogurt, cream), fat and oils (e.g. animal fat, vegetable fat), soups and dressings (vegetable soup, lentil soup, curry sauce), beverages (e.g. tea, coffee, soft drinks, juice) and water intake (e.g. tap water, bottled water).

6.11. Biochemical and physiological measurements

Consenting participants were invited to their PHCC in a 10-hour overnight fasted state. Biochemical measurements were assessed using standard laboratory procedures. Blood was drawn by trained nurses, centrifuged and processed on the same day. Whole blood and serum were placed in plain polystyrene tubes and stored in freezers at -20° C. The lipid profile (triglycerides – TG, total cholesterol - TC, high density lipoprotein cholesterol - HDL-C, and low-density lipoprotein cholesterol - LDL-C) and fasting blood glucose (FBG) were assessed and quantified using routine laboratory analysis (KoneLab, Espoo, Finland). LDL-C concentrations were measured using Friedewald's formula. The biochemical analyser was calibrated routinely prior to the analysis of all serum samples using quality control samples provided by the manufacturer (ThermoFisher Scientific, Espoo, Finland). For validation purposes, randomized samples were sent to King Faisal Specialist Hospital and Research Centre, Riyadh, KSA which served as a reference laboratory. Research nurses measured blood pressure using a clinical mercury manometer. Systolic and diastolic blood pressures were taken twice and the average of both readings was recorded.

6.12. Clinical diagnosis of chronic conditions

The diagnostic criteria for type 2 diabetes mellitus (T2DM) and impaired fasting glucose (IFG) were based on the World Health Organization (WHO) proposed cut-off values for the newly diagnosed (FPG levels of ≥ 7.0 mmol/L (126 mg/dL); IFG with a FPG between 6.1-6.9 mmol/L (110-125 mg/dL); non-diabetics with a FPG of < 6.1 mmol/L (110 mg/dL) (WHO 2006), along with self-report of physician diagnosis and/or intake of anti-diabetes medications.

Participants were considered as having abnormal lipid levels if they self-reported dyslipidaemia or intake of lipid lowering drugs or had lipid levels in the following ranges TC ≥ 5.2 mmol/L and/or TG ≥ 1.7 mmol/L and/or LDL-C ≥ 2.6 mmol/L and/or HDL-C < 1.03 (Expert Panel on Detection 2001). Hypertension diagnosis was based on the recommendations of the Seventh Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (Chobanian et al. 2003). Participants were diagnosed with hypertension if systolic blood pressure was > 140 mmHg and/or diastolic blood pressure of > 90 mmHg, or if participants were on anti-hypertensive medications. Participants were classified as being underweight if BMI < 18 kg/m², normal weight if BMI 18.5-24.9, overweight if BMI 25-29.9 kg/m², and obese if BMI ≥ 30 kg/m² based on WHO classifications (WHO 2004).

6.13. Variables included in the dataset provided by the Saudi collaborators

The data was entered by the team members of the research centre in Saudi Arabia. The data set provided by the collaborators included of 3248 participants coded by a serial

number for each participant, and included age, sex, demographic data, anthropometric measurements, disease history, physical activity, drug intake, systolic blood pressure (mmHg), and diastolic blood pressure (mmHg) (available in Appendix 1).

The dataset included 135 dietary variables collected via a semi-quantitative FFQ (available in Appendix 2). The dataset also included serum FPG (mmol/L), TC (mmol/L), HDL-C (mmol/L), LDL-C (mmol/L), and TG levels (mmol/L). Descriptive statistics of the dataset variables are provided in the next chapter (Chapter 7 – Descriptive characteristics of the 2631 participants of this project).

6.14. Data storage, preparation and cleaning

The research centre provided an electronic dataset of 3248 consenting participants in an Excel sheet. The Excel sheet was imported to IBM SPSS Statistics Version 21 for data preparation and cleaning. The storage and use of data complied with all legislation to data protection with current guidelines of the Warwick University data management directive. Measures to prevent accidental breaches of confidentiality were taken by storing data in a password-protected drive.

Each variable was carefully explored, screened, recoded, labelled, and cross-checked (Bland 2000) using statistical package SPSS Statistics V.21. Graphs and scatterplots were computed to identify outliers. Categorical variables were recoded following the questionnaire coding sheet (demographic and FFQ), and frequency cross tabulation tables were produced to ensure correct coding and values.

Following the dataset cleaning, we were left with 2631 participants who met the inclusion criteria for this study (Figure 6.1.). From the original sample provided ($n =$

3248), 529 participants did not provide dietary data. Comparisons between participants with ($n = 2631$) and without dietary data ($n = 529$) were carried out (Appendix 5). There was a significant difference between participants with and without dietary data; participants without dietary data were younger and generally healthier. This is perhaps the opposite of what might be expected if there is respondent bias, but it is unclear why these data are missing despite attempts to determine this. The main dataset for this thesis includes only those with dietary data so dietary variables can be adjusted for as potential covariates.

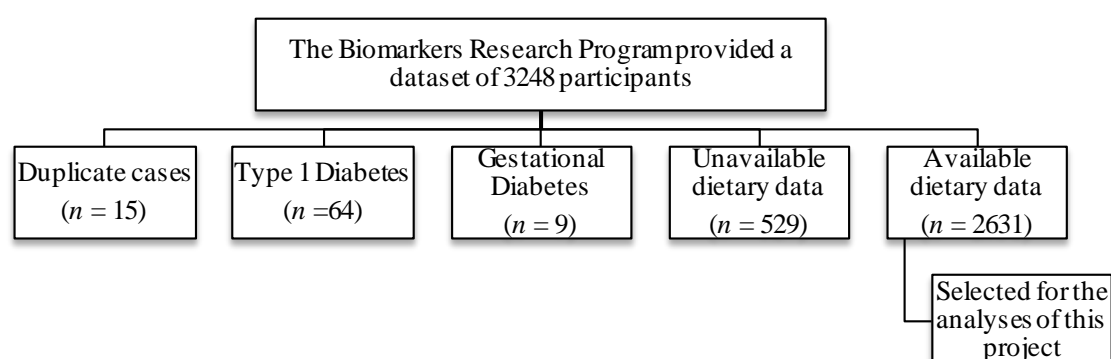


Figure 6.1. Selection of participants for the analyses of this project

6.15. Dietary measurements preparation and cleaning

The dietary dataset included 135 dietary variables which were collected at baseline using a semi-quantitative FFQ (available in Appendix 2). Out of the 135 dietary variables 45 did not report the quantity measures (i.e. cups, grams) because they were not assessed in the questionnaire, 3 questions combined different foods of different nutritional values under one question, 70 reported values that were difficult to interpret (i.e. reported the amount without the frequency, reported the frequency without the

amount, the amount reported was not realistic). The 17 food items that were appropriate for analysis were apple, pear, orange, banana, dates, egg, milk, sugar/honey, brown bread shami, white bread shami, regular brown bread, regular white bread, brown toast, white toast, shaboora, tea and coffee.

6.16. Dietary data entry

The FFQ was built manually using the QBuilder V2.0, and each food item had a unique code which included portion size, and nutritional composition. The nutritional compositions of Arabic foods were obtained from the Arab Food Analysis Programme V1.0 (2007), and the Arabic Encyclopedia of Food and Nutrition (Musaiger 2009). The 2631 participants nutritional data were manually entered into the nutritional software programme QBuilder V2.0. Each case was coded using the same serial code as the BRS dataset. After the entry of each case, the data were checked to identify entry errors. Following that, a random check of entered data was carried out for further confirmation.

6.17. Fieldwork activities

Table 6.1. shows the research activities that were conducted in order to facilitate the completion of this project.

Table 6.1. Fieldwork activities

Research activity	Description	Time period
Field work preparation		
Research costs	The primary investigator applied for additional funding for research costs (£24000). Research funding was managed by the primary investigator and supported by the finance team at Warwick Medical School. This process included bringing the money into Warwick Medical School and then transferring the research costs to the research centre in Saudi Arabia.	Funding application was carried out over two years - £12000 for each year. Money transfer – eight months.
Ethical approval	The primary investigator applied for ethical approval from both Saudi Arabia and the UK.	Saudi ethics – two months. UK ethics – three months
Data collection planning	The primary investigator went to Saudi Arabia twice to visit the primary health care centres, meet up with research nurses, introduce the study and discuss feasibility. The primary investigator emailed the serial number of potential participants to research nurses.	Three months.
Fieldwork		
Data collection of the 2009 survey	Conducted by the primary health care physicians and research nurses and was managed by the Biomarkers Screening Survey (BSR) research group.	NA
Pilot study of the cultural barriers questionnaires ($n = 30$)	The primary investigator carried out the preparation, management and conducted the pilot study. Research nurses approached primary health care attendees, however, the primary investigator carried out the interview, completed the questionnaire and managed the data.	Two months.

Data collection – Food frequency questionnaire calibration	The primary investigator conducted the food frequency questionnaire interview (face to face interviews) and completed the questionnaire. Research nurses were only responsible for the invitation of potential participants.	
Data collection – 24 hour recall interview	The primary investigator conducted two 24 hour recall interviews over the phone and completed the recall. The primary investigator followed up participants and offered a free nutritional consultation for participants who completed the study.	Three months.
Data collection – Cultural barriers interview	The primary investigator conducted the cultural barriers interview (face to face interviews) and completed the questionnaire.	
Biomarkers		
Biomarkers sample selection	The primary investigator generated a computer based random sample ($n = 600$) and sent the serial numbers of the samples to the laboratory in Saudi Arabia. The primary investigator was responsible for the management of this process (i.e. communication and management with the laboratory team).	One week.
Biomarkers sample laboratory analysis	Laboratory technicians of the biomarkers research centre in Saudi Arabia analysed frozen serum samples (vitamin D, selenium and fasting insulin). The results were sent to the primary investigator.	Five months.
Software and data management		
BSR data set cleaning and preparation ($n = 2348$)	Conducted by the primary investigator.	Six months.
Nutritional software preparation	The primary investigator manually built the food frequency questionnaire and imported the nutritional food composition	Two months.

	into Tinuviel software QBuilder V2.0. The primary investigator manually built the 24 hour dietary recall and imported the nutritional food composition into WISP V3.0. software.	
Dietary data entry ($n = 2631$)	The primary investigator manually entered the dietary data into Tinuviel nutritional software QBuilder V2.0.	Six months.
Back translation of the pilot and fieldwork data	All the data were in Arabic language. The primary investigator carried out back translation (Arabic to English) and this was supported by a bilingual researcher.	One month.
Fieldwork data entry – Food frequency questionnaire data ($n = 98$)	The primary investigator manually entered the coded dietary data into Tinuviel nutritional software QBuilder V2.0.	Two weeks.
Fieldwork data entry – two 24 hour dietary recall data ($n = 98$)	The primary investigator manually entered the coded dietary data into WISP V3.0. Tinuviel software. Each participants had two recalls, therefore, 196 recalls were manually entered.	One month.
Fieldwork data entry – Cultural barriers data ($n = 108$)	The primary investigator entered the free text data into word documents, imported to Nvivo software and coded the data using Nvivo software. The primary investigator entered the quantitative data into SPSS.	Two months.

Summary

In this chapter, the Biomarkers Screening in Riyadh survey (2009) methods, the collaborations for this project, the dataset, data preparation and data entry have been described. In the next chapter (Chapter 7), the descriptive characteristics of the project sample ($n = 2631$) will be presented. The next chapter will cover materials and methods, statistical analysis, results and discussion.

7 Descriptive characteristics of the 2631 participants of this project

Introduction

In this chapter, anthropometrics, socio-demographics, diabetes and cardiovascular profiles, physiological, biochemical, and reproductive characteristics of the 2631 participants are presented.

7.1. Materials and methods

The data presented in this chapter are from the Biomarkers Screening Survey (2009) . In brief, the study sample ($n = 2631$) is a sub-sample of the Biomarkers Screening Survey conducted in 2009 in Riyadh, Saudi Arabia. The sample of this project includes Saudi adults (age >18 years), from both sexes who completed the demographic questionnaire and FFQ. Please refer to “Chapter 6 – The Biomarkers Screening in Riyadh (2009) survey methods” for more details of the survey methods and data preparation.

For anthropometric measures, the Biomarkers Screening Survey in Riyadh (2009) and the current project followed the WHO international classification of adult underweight, normal-weight, overweight and obesity according to BMI (WHO 2004) since there are no cultural specific classifications for Saudi Arabian adults (Almajwal et al. 2009). Waist to hip ratio (WHR) was calculated by dividing the waist circumference by the hip circumference (WHO 2011).

Reports on chronic diseases were based on biochemical/physiological measures and/or self-reports. Hypertension diagnosis was based on the recommendations of the Seventh Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (Chobanian et al. 2003). Participants were categorized as hypertensive if systolic blood pressure was >140 mmHg and/or diastolic blood pressure of >90 mmHg, or if participants were on anti-hypertensive medications and/or participants self-reported hypertension from the structured BSR questionnaire.

Diagnostic criteria for type 2 diabetes mellitus (T2DM) and impaired fasting glucose (IFG) were based on the World Health Organization (WHO) proposed cut-off values for the newly diagnosed (FPG levels of ≥ 7.0 mmol/L (126 mg/dL); IFG with a FPG between 6.1-6.9 mmol/L (110-125 mg/dL); non-diabetics with a FPG of <6.1 mmol/L (110 mg/dL) (WHO 2006) along with self-report of physician diagnosis and/or intake of anti-diabetes medications.

Participants were considered as having abnormal lipid levels if they self-reported dyslipidaemia and/or intake of lipid lowering drugs and/or had lipid levels based on the National Cholesterol Education Program (NCEP) (TC ≥ 5.2 mmol/L and/or TG ≥ 1.7 mmol/L and/or LDL-C ≥ 2.6 mmol/L and/or HDL-C <1.03) (Expert Panel on Detection 2001).

7.2. Statistical analysis

Analysis was stratified by sex and diabetes status. Sex stratification was set *a priori* because of the biological and social differences between females and males (Bird et al. 1999), as well as due to the well-established differences in diabetes etiology and natural

history between the two sexes (Donahue et al. 2007, Donahue et al. 2011). Statistical analysis was conducted using the statistical package SPSS Statistics V.21. Continuous variables were described using means and standard deviations, and categorical variables were described as frequencies in percentages. Multivariate analysis was conducted using ANOVA for continuous variables, and chi-square test for categorical variables (Bland 2000).

7.3. Results

Table 7.1. provides a general description of the baseline study participants, including socio-demographic, anthropometric, and clinical characteristics, as well as chronic conditions. Approximately equal proportions of females and males (48.7% vs 51.3%, respectively) participated in the study, with a mean age of 40.8 years with males significantly older than females. More than half of the sample was either overweight or obese (33.3% and 41.2% respectively) with a mean BMI of 29.16 kg/m². Women had a significantly higher BMI than men (30.02 vs. 28.34 kg/m² respectively).

The mean values of WC were 94.11 cm for the overall sample, and males had a wider WC (97.04 cm) in comparison to females (91.00 cm) $p < 0.001$. Sagittal abdominal diameter (SAD) was wide in both females and males with a mean value of nearly 24 cm. The prevalence of hypertension was 24.4%, lipid abnormalities was 93.9% and diabetes 29.3% for the overall sample. However, chronic conditions were significantly more prevalent amongst males in comparison to females ($p < 0.001$). Over 80% of participants reported a family history of diabetes, and the majority reported a first-degree family history of diabetes (44.9%).

Mean values for physiological and biochemical parameters were as follows: systolic blood pressure 120.26 mmHg, diastolic blood pressure 77.41 mmHg, FPG 6.89 mmol/L, and lipid profile (TC 5.08, TG 1.75, LDL-C 3.40, and HDL-C 0.86 mmol/L).

Table 7.1. Baseline* characteristics of the overall sample

Variable	Overall	Females	Males	<i>p</i>
<i>n</i>	2631	1280	1351	
Age (yrs)	40.80±15.47	38.55±13.90	42.92±16.56	<0.001
Sex				
Female	48.7% (1280)			
Male	51.3% (1351)			
Weight (kg)	76.63±17.32	73.13±16.82	79.95±17.14	<0.001
BMI (kg/m²)	29.16±6.36	30.02±6.71	28.34±5.90	<0.001
Underweight	3.5% (91)	3.9% (49)	3.2% (42)	<0.001
Normal weight	22.0% (568)	19.0% (238)	24.9% (330)	
Overweight	33.3% (858)	29.4% (369)	36.9% (489)	
Obese	41.2% (1062)	47.7% (599)	35.0% (463)	
WC (cm)	94.11±15.83	91.00±15.67	97.04±15.42	<0.001
Hips (cm)	105.14±15.27	106.87±14.64	103.53±15.67	<0.001
WHR	0.90±0.12	0.85±0.10	0.94±0.12	<0.001
SAD (cm)	23.90±8.19	23.70±8.97	24.08±7.45	0.304
Systolic (mmHg)	120.26±14.41	117.72±14.02	122.67±14.37	<0.001
Diastolic (mmHg)	77.41±8.62	75.78±8.52	78.96±8.43	<0.001
FPG (mmol/L)	6.89±3.62	6.66±3.42	7.11±3.78	<0.001
TC (mmol/L)	5.08±1.21	5.06±1.18	5.10±1.24	0.450
TG (mmol/L)	1.75±1.12	1.51±0.89	1.97±1.26	<0.001
LDL-C (mmol/L)	3.40±1.05	3.35±1.00	3.45±1.09	0.013
HDL-C (mmol/L)	0.86±0.34	1.00±0.33	0.72±0.28	<0.001
Free from HTN	75.6% (1713)	79.9% (882)	71.5% (831)	<0.001
HTN	24.4% (553)	20.1% (222)	28.5% (331)	
NDM	60.2% (1585)	64.2% (822)	56.5% (763)	<0.001
PDM	10.5% (276)	10.4% (133)	10.6% (143)	
T2DM	29.3% (770)	25.4% (325)	32.9% (445)	
No family history	17.5% (345)	16.8% (165)	18.2% (180)	0.023
1 st degree family history	44.9% (884)	42.3% (415)	47.5% (469)	
2 nd degree family history	14.1% (278)	15.1% (148)	13.2% (130)	
1 st & 2 nd degree family history	23.4% (461)	25.8% (253)	21.1% (208)	
Free from lipid abnormalities	6.1% (157)	9.0% (113)	3.3% (44)	<0.001
Lipid abnormalities	93.9% (2437)	91.0% (1146)	96.7% (1291)	

* Percentage (*n*) or mean values ± SD

p value indicates the statistical difference between females and males.

BMI indicates body mass index; **Underweight** < 18.5 kg/m², **Normal weight** 18.5-24.99 kg/m², **Overweight** ≥ 25 kg/m², **Obese** ≥ 30 kg/m²; **WC** indicates waist circumference; **WHR** indicates waist to hip ratio (waist (cm)/hips (cm)); **SAD** indicates sagittal abdominal diameter in cm; **FPG** indicates fasting plasma glucose; **TC** indicates total cholesterol; **TG** indicates triglycerides; **HTN** indicates self-reported hypertension, or use of HTN drugs or systolic ≥140 mmHg or diastolic ≥90 mmHg; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **PDM**: pre-diabetes (self-reported pre-diabetes and/or FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **T2DM**: type 2 diabetes mellitus (self-reported T2DM and/or FPG ≥7.0 mmol/L; ≥126 mg/dL); **Family history of diabetes**: 1st degree includes father, mother, siblings or children. 2nd degree includes uncle, aunt, grandparents or grandchildren. **Lipid abnormalities** indicates self-reported dyslipidaemia and/or intake of lipid lowering drugs and/or lipid levels (TC ≥5.2 mmol/L and/or TG ≥1.7 mmol/L and/or LDL-C ≥ 2.6 mmol/L and/or HDL-C <1.03).

A) Socio-demographic characteristics

Table 7.2. provides the socio-demographic characteristics of the overall sample stratified by sex and diabetes groups. The mean age increased significantly ($p < 0.001$) amongst diabetes categories, no diabetes mellitus (NDM) – pre diabetes mellitus (PDM) - type 2 diabetes mellitus (T2DM), in both females and males, however, males were older (NDM 37.68, PDM 40.35, T2DM 52.73 years) in comparison to females (NDM 34.01, PDM 41.53, T2DM 48.85 years). The majority of participants with diabetes were married (females 77.2%, and males 92.7%). The prevalence of consanguinity and consanguinity degree did not significantly differ amongst diabetes categories in both females and males. However, females with diabetes were more likely to have consanguineous marriages (64.4%) in comparison to males with diabetes (59.0%), but there was no significant difference between groups. Illiteracy was more prevalent amongst participants with diabetes (females 65.4%, and males 26.9%) in comparison to participants with no diabetes (females 28.9%, and males 12.1%). Conversely, females and males with no diabetes had a college degree or higher (30.6%, 36.2% respectively) in comparison to females and males with diabetes (6.8%, 19.5% respectively). There was a 10% increase in unemployment amongst females with T2DM (89.4%) in comparison to non-diabetics (79.6%), accompanied by a lower income.

Table 7.2. Socio-demographic characteristics*

Chapter 7: Descriptive characteristics of the 2631 participants of this project

Variable	Females (<i>n</i> = 1280)				Males (<i>n</i> = 1351)			
	NDM	PDM	T2DM	<i>p</i>	NDM	PDM	T2DM	<i>p</i>
<i>n</i>	822	133	325		763	143	445	
Age (yrs)	34.01±12.07	41.53±14.02	48.85±12.28	<0.001	37.68±15.47	40.35±15.15	52.73±14.29	<0.001
Marital status								
Single	32.4% (262)	17.6% (23)	6.2% (20)	<0.001	30.3% (226)	22.5% (32)	6.8% (30)	<0.001
Married	60.3% (487)	71.0% (93)	77.2% (772)		69.4% (517)	76.8% (109)	92.7% (407)	
Divorced	3.3% (27)	1.5% (2)	2.2% (7)		0.1% (1)	0.0% (0)	0.0% (0)	
Widowed	4.0% (32)	9.9% (13)	14.5% (47)		0.1% (1)	0.7% (1)	0.5% (2)	
Consanguinity								
Yes	59.3% (285)	61.7% (58)	64.4% (159)	0.403	58.7% (279)	61.3% (65)	59.0% (220)	0.885
No	40.7% (196)	38.3% (36)	35.6% (88)		41.3% (196)	38.7% (41)	41.0% (153)	
Consanguinity degree								
1 st degree	59.9% (163)	72.0% (36)	57.3% (90)	0.178	54.8% (142)	61.3% (38)	57.1% (128)	0.634
2 nd degree	40.1% (109)	28.0% (14)	42.7% (67)		45.2% (117)	38.7% (24)	42.9% (96)	
Education level								
Illiterate	28.9% (226)	46.3% (57)	65.4% (202)	<0.001	12.1% (86)	10.8% (14)	26.9% (113)	<0.001
Pre-college	40.5% (316)	36.6% (45)	27.8% (86)		51.7% (367)	55.4% (72)	53.6% (225)	
College or Higher	30.6% (239)	17.1% (21)	6.8% (21)		36.2% (257)	33.8% (44)	19.5% (82)	
Employment								
Unemployed	79.6% (477)	79.6% (74)	89.4% (227)	0.007	22.6% (147)	17.6% (21)	10.9% (44)	<0.001
Retired	1.2% (7)	2.2% (2)	0.0% (0)		13.5% (88)	18.5% (22)	37.3% (150)	
Employed	19.2% (115)	18.3% (17)	10.6% (27)		63.5% (415)	63.9% (76)	51.7% (208)	
Annual income (SR)								
< 5000	76.9% (475)	71.3% (67)	84.0% (194)	0.068	37.0% (253)	34.1% (44)	32.4% (136)	0.117
5000-10 000	11.5% (71)	12.8% (12)	9.1% (21)		28.4% (194)	29.5% (38)	25.0% (105)	
> 10 000	11.7% (72)	16.0% (15)	6.9% (16)		34.6% (237)	36.4% (47)	42.6% (179)	

* Percentage (*n*) or mean values ± SD. *p* value indicates the statistical difference between diabetes groups; **Consanguinity degree:** 1st degree is first cousins, 2nd degree is any other.

B) Anthropometric and lifestyle behaviour characteristics

Table 7.3. provides anthropometric characteristics of the overall sample stratified by sex and diabetes group. Adiposity measurements (weight, BMI, WC, hips, WHR, and SAD) increased significantly amongst diabetes groups in both females and males. Overweight and obesity increased amongst diabetes groups, however females had a higher prevalence of obesity (NDM 39.8%, PDM 55.4%, T2DM 64.5%, $p < 0.001$) in comparison to males (NDM 30.5%, PDM 39.9%, T2MD 41.1%, $p < 0.001$). The “pear” and “apple” shaped body was clear amongst females and males respectively, where females had a higher hip circumference (NDM 105.61, PDM 108.53, T2DM 109.7 cm, $p < 0.001$) whilst males had a higher WC (NDM 94.29, PDM 97.37, T2DM 101.64 cm, $p < 0.001$) and SAD (NDM 23.26, PDM 25.10, T2DM 25.11 cm, $p < 0.001$).

There was a non-significant ($p = 0.218$) higher prevalence of smoking amongst males with no diabetes (19.5%) in comparison to diabetics (14.4%), but smoking duration was longer in T2DM at 16.21 years in comparison to non-diabetics at 11.46 years. Participants with no diabetes were more active in comparison to those with diabetes in both females (NDM 87%, T2DM 84%, $p = 0.164$) and males (NDM 78.7%, T2DM 65.1%, $p < 0.001$). The majority of participants with T2DM who reported the intensity of physical activity were engaged in mild levels of physical activity (females 36.8%, males 29.5%). Mean levels of sleeping hours decreased significantly across diabetes groups in both females (NDM 7.91, PDM 7.68, T2DM 7.45 hours, $p < 0.001$), and males (NDM 7.72, PDM 7.60, T2DM 7.45 hours, $p = 0.019$).

Table 7.3. Anthropometric characteristics and lifestyle behaviours*

Variable	Females (<i>n</i> = 1280)				Males (<i>n</i> = 1351)			
	NDM	PDM	T2DM	<i>p</i>	NDM	PDM	T2DM	<i>p</i>
Weight (kg)	70.69±16.82	74.93±16.37	78.54±15.66	<0.001	78.27± 17.47	81.80± 17.52	82.27± 16.13	<0.001
Height (cm)	156.49±6.37	155.25±6.34	155.46±6.74	0.016	168.57± 7.52	167.96± 6.66	166.93± 7.38	0.001
BMI (kg/m ²)	28.87±6.69	31.09±6.695	32.51±6.00	<0.001	27.52± 5.78	28.94± 5.80	29.57± 5.91	<0.001
BMI categories								
Underweight	5.3% (43)	2.3% (3)	0.9% (3)	<0.001	4.8% (36)	2.2% (3)	0.7% (3)	<0.001
Normal	24.2% (195)	15.4% (20)	7.2% (23)		29.3% (220)	23.2% (32)	17.9% (78)	
Overweight	30.6% (247)	26.9% (35)	27.4% (87)		35.4% (266)	34.8% (48)	40.2% (175)	
Obese	39.8% (321)	55.4% (72)	64.5% (206)		30.5% (229)	39.9% (55)	41.1% (179)	
WC (cm)	87.96±15.42	94.96±16.11	97.56±13.66	<0.001	94.29± 15.30	97.37± 16.25	101.64± 14.24	<0.001
Hips (cm)	105.61±14.73	108.53±15.34	109.70±13.65	<0.001	102.38±15.29	104.14± 15.98	105.32± 16.07	0.011
WHR	0.83±0.11	0.86±0.08	0.89±0.09	<0.001	0.9283±0.12	0.94± 0.11	0.97± 0.13	<0.001
SAD (cm)	23.11±9.85	24.55±6.31	24.98±7.11	0.017	23.26±7.96	25.10±8.70	25.11±5.86	<0.001
Smoking status								
Never-smokers	99.5% (590)	100.0% (86)	98.6% (219)	0.398	68.6% (455)	67.2% (90)	70.6% (274)	0.218
Former-smokers	0.0% (0)	0.0% (0)	0.5% (1)		11.9% (79)	14.9% (20)	14.9% (58)	
Current smokers	0.5% (3)	0.0% (0)	0.9% (2)		19.5% (129)	17.9% (24)	14.4% (56)	
Smoking duration (yrs)	4.00±4.24	-	20.00±21.21	0.405	11.46± 9.22	14.54± 10.58	16.21± 11.19	0.002
Quitting smoking (yrs)	NA	NA	9.02±8.44	8.44±8.35	14.44±10.59	0.010		
Physical activity (PA)								
Active	87.0% (677)	81.1% (99)	84.4% (259)	0.164	78.7% (586)	79.6% (113)	65.1% (280)	<0.001
Non-active	13.0% (101)	18.9% (23)	15.6% (48)		21.3% (159)	20.4% (29)	34.9% (150)	
PA frequency								
Non-active	13.0% (101)	18.9% (23)	15.6% (48)	0.607	21.3% (159)	20.4% (29)	34.8% (150)	<0.001

Not reported	12.7% (99)	13.9% (17)	9.4% (29)		7.0% (52)	9.9% (14)	7.0% (30)	
Once/month	2.3% (18)	1.6% (2)	2.0% (6)		3.8% (28)	2.1% (3)	2.3% (10)	
Few times/month	5.8% (45)	4.1% (5)	6.2% (19)		9.3% (69)	12.0% (17)	9.0% (39)	
1-2 times/week	8.6% (67)	9.0% (11)	10.4% (32)		17.3% (129)	17.6% (25)	11.6% (50)	
3-4 times/week	12.5% (97)	15.6% (19)	11.4% (35)		17.3% (129)	16.9% (24)	12.8% (55)	
Daily	45.0% (350)	36.9% (45)	45.0% (138)		24.0% (179)	21.1% (30)	22.5% (97)	
PA intensity								
Non-active	13.0% (101)	18.9% (23)	15.6% (48)	0.010	21.3% (159)	20.4% (29)	34.9% (150)	<0.001
Not reported	24.6% (191)	18.9% (23)	22.1% (68)		13.2% (98)	12.0% (17)	8.6% (17)	
Mild levels	27.8% (216)	30.3% (37)	36.8% (113)		26.6% (198)	27.5% (39)	29.5% (127)	
Moderate levels (1)	11.8% (92)	16.4% (20)	12.1% (37)		7.1% (53)	13.4% (19)	9.3% (40)	
Moderate levels (2)	20.1% (156)	14.8% (18)	12.4% (38)		14.1% (105)	15.5% (22)	12.8% (55)	
High levels	1.7% (13)	0.0% (0)	0.3% (1)		6.2% (46)	4.2% (6)	1.9% (8)	
Vigorous levels	1.2% (9)	0.8% (1)	0.7% (2)		11.5% (86)	7.0% (10)	3.0% (13)	
Sleeping hours	7.92±1.48	7.74±1.45	7.49±1.36	<0.001	7.73±1.43	7.60±1.31	7.45±1.49	0.013
Sleeping hours								
< 6 Hours	3.2% (22)	4.0% (4)	7.7% (20)	0.032	4.0% (26)	5.7% (7)	7.9% (29)	0.057
6-8 Hours	73.6% (500)	76.0% (76)	73.7% (191)		73.9% (478)	72.4% (89)	74.7% (275)	
> 8 Hours	23.1% (157)	20.0% (20)	18.5% (48)		22.1% (143)	22.0% (27)	17.4% (64)	
Quality of sleep								
Disrupted	47.5% (309)	42.1% (40)	51.4% (126)	0.282	41.8% (267)	52.5% (64)	46.5% (164)	0.064
Non-disrupted	52.5% (341)	57.9% (55)	48.6% (119)		58.2% (371)	47.5% (58)	53.5% (189)	

* Percentage (n) or mean values ± SD

p value indicates the statistical difference between diabetes groups.

BMI indicates body mass index; **BMI categories:** Underweight < 18.5 kg/m², Normal weight 18.5-24.99 kg/m², Overweight ≥ 25 kg/m², Obese ≥ 30 kg/m²; **WC** indicates waist circumference; **WHR** indicates waist to hip ratio (waist (cm)/hips (cm)); **SAD** indicates sagittal abdominal diameter in cm; **PA levels:** Mild levels: washing dishes, walking, Moderate (1): table tennis, Moderate (2): brisk walk, High: tennis, volleyball, Vigorous: running, cycling.

C) Blood pressure and lipid parameters

Table 7.4. provides the blood pressure and lipid parameters of the overall sample stratified by sex and diabetes group. Blood pressure parameters increased in both females (Systolic: NDM 114.04, PDM 120.07, T2DM 125.96 mmHg, Diastolic: NDM 73.94, PDM 77.05, T2DM 79.83 mmHg, $p < 0.001$) and males (Systolic: NDM 118.77, 122.63, 129.05 mmHg, Diastolic: NDM 77.22, PDM 79.63, T2DM 81.59 mmHg, $p < 0.001$) with T2DM. The lipid profile significantly ($p < 0.001$) deteriorated across diabetes groups in both females and males. Females and males with diabetes had higher levels of TC, TG, LDL-C, and a lower level of HDL-C in comparison to non-diabetics.

D) Cardiovascular profile

Table 7.5. provides the cardiovascular profile of the overall sample stratified by sex and diabetes groups. The prevalence of cardiovascular conditions was higher in the diabetic group for both sexes. A significant increase in the prevalence of hypertension was observed across diabetes groups in both females (NDM 10.0%, PDM 22.7%, T2DM 43.9%, $p < 0.001$) and males (NDM 16.5%, PDM 26.0%, T2DM 48.6%, $p < 0.001$). The prevalence of lipid abnormalities was high across groups, but the prevalence was higher in the diabetes group in both females (NDM 87.7%, PDM 94.7%, T2DM 97.8%, $p < 0.001$) and males (NDM 95.2%, PDM 96.5%, T2DM 99.3%, $p = 0.001$). The prevalence of coronary heart disease (CHD) was higher in participants with diabetes, however, it was more prevalent in males (NDM 3.5%, PDM 4.2%, T2DM 23.1%, $p < 0.001$) than in females (NDM 1.5%, PDM 3.0%, T2DM 17.5%, $p < 0.001$).

E) Diabetes-related profile

Table 7.6. provides the diabetes profile of the overall sample stratified by sex and diabetes groups. FPG levels doubled in the diabetes group in comparison to non diabetics with levels at 10.75 mmol/L in females and 10.65 mmol/L in males with T2DM. Over 50% of participants with T2DM reported a family history of diabetes; first-degree family history was the most prevalent and increased across diabetes groups in both females (NDM 39.0%, PDM 38.3% , T2DM 51.8% , $p < 0.001$) and males (NDM 43.3%, PDM 48.6%, T2DM 54.5%, $p = 0.008$). Nearly 40% of females with T2DM were unaware of their condition, and 34.6% of males with T2DM were unaware of their diabetes at the time of the survey (2009).

Table 7.4. Blood pressure and lipid parameters*

Variable	Females (<i>n</i> = 1280)				Males (<i>n</i> = 1351)			
	NDM	PDM	T2DM	<i>p</i>	NDM	PDM	T2DM	<i>p</i>
Systolic (mmHg)	114.04±12.10	120.07±13.18	125.96±15.15	<0.001	118.77±12.87	122.63±12.37	129.05±15.03	<0.001
Diastolic (mmHg)	73.94±8.20	77.05±7.01	79.83±8.41	<0.001	77.22± 7.94	79.63±7.69	81.59±8.75	<0.001
TC (mmol/L)	4.87±1.14	5.33±1.00	5.44±1.23	<0.001	4.90±1.11	5.15±1.27	5.42±1.36	<0.001
TG (mmol/L)	1.29±0.66	1.47±0.70	2.07±1.18	<0.001	1.67±1.03	2.14±1.29	2.44±1.46	<0.001
LDL-C (mmol/L)	3.24±1.01	3.58±0.89	3.51±0.99	<0.001	3.37±1.02	3.50±1.16	3.58±1.18	0.007
HDL-C (mmol/L)	1.01±0.33	1.04±0.32	0.95±0.34	0.013	0.75±0.29	0.67±0.26	0.68±0.27	<0.001

* Mean values ± SD

p value indicates the statistical difference between diabetes groups.

FPG indicates fasting plasma glucose; TC indicates total cholesterol; TG indicated triglycerides; LDL-C indicates low-density lipoprotein; HDL-C indicates high-density lipoprotein.

Table 7.5. Cardiovascular profile*

Variable	Females (n = 1280)				Males (n = 1351)			
	NDM	PDM	T2DM	p	NDM	PDM	T2DM	p
Non hypertensive	90.0% (630)	77.3% (92)	56.1% (160)	<0.001	83.5% (536)	74.0% (91)	51.4% (204)	<0.001
Hypertensive	10.0% (70)	22.7% (27)	43.9% (125)		16.5% (106)	26.0% (32)	48.6% (193)	
Free from lipid abnormalities	12.3% (99)	5.3% (7)	2.2% (7)	<0.001	4.8% (36)	3.5% (5)	0.7% (3)	0.001
Lipid abnormalities	87.7% (706)	94.7% (125)	97.8% (315)		95.2% (713)	96.5% (138)	99.3% (440)	
Coronary heart disease (CHD)								
Free from CHD	98.5% (810)	97.0% (129)	82.5% (268)	<0.001	96.5% (736)	95.8% (137)	76.9% (342)	<0.001
Report CHD ³	1.5% (12)	3.0% (4)	17.5% (57)		3.5% (27)	4.2% (6)	23.1% (103)	
Medical history (self-reported)								
Reported Asthma	5.1% (42)	4.5% (6)	3.4% (11)	0.454	6.3% (48)	4.9% (7)	2.9% (13)	0.035
Not reported	94.9% (780)	95.5% (127)	96.6% (314)		93.7% (715)	95.1% (136)	97.1% (432)	
Reported cancer	0.1% (1)	0.0% (0)	0.3% (1)	0.688	0.1% (1)	0.7% (1)	0.0% (0)	0.164
Not reported	99.9% (821)	100.0% (133)	99.7% (324)		99.9% (762)	99.3% (142)	100.0% (445)	
Reported Liver disease	0.1% (1)	0.8% (1)	0.0%	0.166	0.4% (3)	0.7% (1)	0.4% (2)	0.880
Not reported	99.9% (821)	99.2% (132)	100.0% (325)		99.6% (760)	99.3% (142)	99.6% (443)	
Reported Kidney disease	0.1% (1)	0.0% (0)	0.6% (2)	0.249	0.3% (2)	0.0% (0)	0.7% (3)	0.389
Not reported	99.9% (821)	100.0% (133)	99.4% (323)		99.7% (761)	100.0% (143)	99.3% (442)	

* Percentage (*n*)*p* statistical difference between diabetes groups.

Hypertensive indicates self-reported and/or hypertension drugs and/or systolic ≥ 140 mmHg or diastolic ≥ 90 mmHg; **lipid abnormalities** indicates self-reported and/or intake of lipid lowering drugs and/or lipid levels (TC ≥ 5.2 mmol/L and/or TG ≥ 1.7 mmol/L and/or LDL-C ≥ 2.6 mmol/L and/or HDL-C < 1.03); **Reported CHD** indicates participants who self-reported CHD drugs or presence CHD.

Table 7.6. Diabetes profile*

Variable	Females (<i>n</i> = 1280)				Males (<i>n</i> = 1351)			
	NDM	PDM	T2DM	<i>p</i>	NDM	PDM	T2DM	<i>p</i>
FPG (mmol/L)	5.08±0.56	6.36±0.32	10.75±4.69	<0.001	5.14± 0.59	6.43±0.28	10.65±4.83	<0.001
Family history of DM ¹								
No history	18.3% (115)	21.3% (20)	11.7% (30)	<0.001	20.8% (116)	15.9% (17)	14.6% (47)	0.008
1 st degree	39.0% (246)	38.3% (36)	51.8% (133)		43.3% (241)	48.6% (52)	54.5% (176)	
2 nd degree	17.6% (111)	18.1% (17)	7.8% (20)		15.6% (87)	13.1% (14)	9.0% (29)	
1 st & 2 nd degree	25.1% (158)	22.3% (21)	28.8% (74)		20.3% (113)	22.4% (24)	22.0% (71)	
Diabetes status & reporting ²								
NDM	100.0% (822)	0.0% (0)	0.0% (0)	<0.001	100.0% (763)	0.0% (0)	0.0% (0)	<0.001
SR-PDM	0.0% (0)	7.5% (10)	0.0% (0)		0.0% (0)	2.8% (4)	0.0% (0)	
UA-PDM	0.0% (0)	92.5% (92.5%)	0.0% (0)		0.0% (0)	97.2% (139)	0.0% (0)	
SR-T2DM	0.0% (0)	0.0% (0)	60.6% (197)		0.0% (0)	0.0% (0)	65.4% (291)	
UA-T2DM	0.0% (0)	0.0% (0)	39.4% (128)		0.0% (0)	0.0% (0)	34.6% (154)	
Diabetes duration (yrs)	-	1.00±.	8.39±5.96	0.220	-	2.00±.	8.65±6.96	0.343
DM drugs ³								
Insulin	0.0% (0)	0.0% (0)	23.9% (16)	NA	0.0% (0)	0.0% (0)	16.2% (21)	NA
SU's	0.0% (0)	0.0% (0)	47.8% (32)		0.0% (0)	0.0% (0)	52.3% (68)	
Metformin	0.0% (0)	0.0% (0)	28.4% (19)		0.0% (0)	0.0% (0)	30.8% (40)	
Other OHG	0.0% (0)	0.0% (0)	0.0% (0)		0.0% (0)	0.0% (0)	0.8% (1)	

* Percentages (n) or mean values ± SD

p statistical difference between diabetes groups; **1st degree** includes father, mother, siblings or children, **2nd degree** includes uncle, aunt, grandparents or grandchildren; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **SR - PDM**: self-reported pre-diabetes, **UA-PDM**: unaware of pre-diabetes at the time of the 2009 survey (FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **SR-T2DM**: self-reported type 2 diabetes mellitus, **UA-T2DM**: unaware of type 2 diabetes at the time of the 2009 survey (FPG ≥7.0 mmol/L; ≥126 mg/dL); **3. SU's** indicate Sulfonylureas, **OHG**: oral hypoglycaemic agents.

F) Reproductive profile and the prevalence gestational diabetes history in females ($n = 1280$)

Table 7.7. provides the reproductive characteristics in females. The mean age of menarche was 13.42 years, and was not significantly different ($p = 0.760$) across diabetes groups. The mean age of first pregnancy of Saudi females was 20.21 years; females with T2DM seem to conceive at a younger age (19.51 years) in comparison to females with pre-diabetes (20.11 years) and with no diabetes (20.60 years, $p = 0.012$). The prevalence of gestational diabetes was 5.5% in the total female sample, whilst the prevalence was significantly higher ($p < 0.001$) in females with diabetes (13.7%) in comparison to females with pre-diabetes (2.8%) and with no diabetes (2.1%).

Table 7.7. Reproductive profile*

Variable	Overall	NDM	PDM	T2DM	<i>p</i>
Menarche age (yrs)	13.42±1.56	13.42±1.53	13.51±1.40	13.39±1.72	0.760
Age at 1st pregnancy (yrs)	20.21±4.09	20.60±3.97	20.11±4.31	19.51±4.19	0.012
History of GDM					
No GDM History	94.5% (936)	97.9% (592)	97.2% (104)	86.3% (240)	<0.001
GDM History	5.5% (54)	2.1% (13)	2.8% (3)	13.7% (38)	

* Percentages (*n*) or mean values ± SD.

p statistical difference between diabetes groups.

GDM indicates gestational diabetes mellitus.

7.4. Discussion

In this chapter, the participant's ($n = 2631$) characteristics, including diabetes risk factors (socio-demographic, anthropometrics and major lifestyle behaviours, physiological, biochemical, cardiovascular, and reproductive characteristics) from the BSR dataset have been explored and presented. The prevalence of glucose abnormalities in this study was high, the prevalence of IFG was 10.5%, and the prevalence of T2DM was 29.3%. Males were significantly older than females, and a significant linear increase in age across the three groups (NDM, PDM, and T2DM) was observed. Aging is a traditional risk factor for diabetes (Boyle et al. 2001, Lindström et al. 2003, Glümer et al. 2004, Wilson et al. 2007), and that was clearly observed where participants with prevalent diabetes were significantly older.

The prevalence of diabetes in this study was comparable to a recent survey to estimate diabetes prevalence, the Riyadh-cohort 2 survey (Al-Daghri et al. 2011). The survey was conducted in Riyadh, the same city of this study, and the prevalence of T2DM was 31.6%. However, the Riyadh-cohort 2 survey included a different age range (7-80 years) in comparison to this study. Diabetes diagnosis was based on FPG values only (Al-Daghri et al. 2011), whilst in the present study both self-report of a physician diagnosis and use of anti-diabetes medication were also included as diagnostic criteria for T2DM, and participants of this study were older (≥ 18 years).

The mean FPG levels of the overall sample were high, and males had significantly higher levels (7.11 mmol/L) than females (6.66 mmol/L, $p < 0.001$). Males had a significantly higher prevalence of glucose abnormalities in comparison to females, where nearly 33% of males had T2DM in comparison to a quarter of females. The sex

differences for diabetes prevalence in Saudi Arabia have been reported in previous surveys, and in line with the results presented in the current project, Saudi females tend to have a lower prevalence of diabetes in comparison to males (Al-Nozha et al. 2004, Al-Daghri et al. 2011).

Despite the readily available access to a free health service in Riyadh, a striking 92.5% of females and 97.2% of males were not aware of their IFG levels. Moreover, 39.4% of females and 34.5% of males with diabetes were not aware of their condition at the time of the survey. Undiagnosed diabetes has been reported in previous local surveys, Al Nozha *et al.* reported a prevalence of 27.9% of undiagnosed diabetes out of 16,917 cases of diabetes in Saudi Arabia (Al-Nozha et al. 2004). Al Nuaim reported a higher prevalence (56%) of newly diagnosed diabetes amongst Saudi adults, however, both random plasma glucose and a 75 oral glucose tolerance were used for diabetes diagnosis (Al-Nuaim 1997). Undiagnosed diabetes is a larger issue in Saudi in comparison to other countries; for example, in Iran the prevalence of undiagnosed cases was 5.1% for diabetes and 8.7% for IFG (Hadaegh et al. 2008). Around 8% of diabetes cases are unaware of their condition in Germany (Haastert et al. 2003), whilst it is lower in Canada (2.2%) (Leiter et al. 2001) and the US (2.8%) (Cowie et al. 2006). Nevertheless, the lower prevalence of diabetes in these countries should be considered.

Adiposity is a major risk factor for T2DM, and different adiposity measures in relation to T2DM have been explored (Okosun et al. 1998, Jia et al. 2007, Li et al. 2010). In this study, a significant sex difference for all anthropometrics measures ($p < 0.05$) was observed. Saudi adults, with or without glucose abnormalities, seem to be heavy. The mean BMI was 29.16 kg/m² for the overall sample, 30.02 kg/m² for females, and 28.34 kg/m² for males. Saudi adults BMI is comparable to US adults (28.7 kg/m² for both

females and males), however it seems that Saudi women are heavier in comparison to US women (Flegal et al. 2012). Participants with T2DM had a significantly ($p < 0.001$) heavier body mass in comparison to other groups (NDM, PDM), and females with diabetes had a higher BMI (32.51 kg/m^2) in comparison to males with T2DM (29.57 kg/m^2). The findings show a high prevalence of overweight and obesity in the total sample (33.3% , 41.2% respectively) which is similar to local observational studies in the central region in Saudi Arabia (Al-Nozha et al. 2005, Al-Daghri et al. 2011).

The overall prevalence of overweight and obesity among adults with T2DM was 34.7% and 51.1% respectively. These figures are similar to US populations, for example the prevalence of obesity amongst adults with diagnosed diabetes was 54.8% in the NHANES study (CDC 2004). However, men had a significantly higher prevalence of overweight than females, 36.9% compared to 29.4% respectively in the overall sample, and a similar trend was observed in participants with T2DM. Females had a higher prevalence of obesity, 47.7% compared to 35.0% respectively in the overall sample, and a striking 64.5% of females with T2DM had a $\text{BMI} \geq 30 \text{ kg/m}^2$. The sex difference for the prevalence of overweight and obesity found in this study is in line with other observational studies originating from Saudi Arabia (Al-Nuaim et al. 1996, Al-Nozha et al. 2005, Al-Othaimen et al. 2006, Al-Daghri et al. 2011, Habib 2013). A similar cross-sectional study conducted in the UK reported similar findings to the current study, where males with diabetes had a higher prevalence of overweight compared to females (60.5% vs. 39.5%) and the overall prevalence of obesity amongst T2DM was 52% in 3637 participants (Daousi et al. 2006).

Central adiposity was clear in the study sample, where the mean WC of the overall sample was 94.11 cm, and males had significantly higher WC (97.04 cm) in comparison

to females (91.0 cm). The mean SAD was 23.0 cm for the total sample and was significantly higher across diabetes groups in both males and females. Another Saudi population-based cross-sectional study reported similar findings, where males had a higher WC (94.2 cm) in comparison to females (90.3 cm), however, SAD was not assessed in this survey (Al-Nozha et al. 2007). Although our findings are comparable to the overall mean values of WC in the Middle Eastern region (98.2 cm for males and 93.4 cm for females (Balkau et al. 2007), Saudi adults seem to have a wider WC in comparison to some neighboring countries. For instance, the mean values of WC in Iranian adults is 88.67 cm (Esteghamati et al. 2009), 81.2 cm in Omani males, and 84.4 cm in Omani females (Al-Lawati et al. 2003). Males in the current study have a wider WC in comparison to African men, such as Nigerians (77.7 cm), and Jamaicans (80.9 cm) (Okosun et al. 1998), whilst females in the current study have a wider WC in comparison to European females (91 cm vs. 82.8 cm) (Gram et al. 2006). Nevertheless, the average WC of Saudi adults is comparable to national mean values from other developed countries, such as the US, where the mean WC in males is 98.6 cm and 92.2 cm in females (Ford et al. 2003).

Saudi adults may have an increased risk of metabolic complications according to the WHO cut-off points for WC and risk of metabolic complications (> 94 cm for males, and > 80 cm for females) (WHO 2011), and the International Diabetes Federation (IDF) cut-offs (> 94 cm for males, and > 80 cm for females) (IDF 2006). This was confirmed in the current study when observing the WC across the three groups (NDM, PDM, T2DM) in both females and males. A significant 10 cm increase in WC was observed in T2DM females in comparison to NDM females, and similarly males with prevalent diabetes had a significantly higher WC (101 cm) in comparison to NDM males (94 cm, $p < 0.001$).

Although SAD is associated with diabetes (Anjana et al. 2004), diabetes markers (Risérus et al. 2004), and diabetes risk factors (Valsamakis et al. 2004) in other contexts, it has not been previously explored as a risk factor in Saudi and neighboring countries (Al-Riyami et al. 2003, Al-Nozha et al. 2005, Bouguerra et al. 2006, Balkau et al. 2007, Esteghamati et al. 2009). The mean values of SAD were 23.9 in the overall sample. SAD was significantly higher in T2DM participants in comparison to other groups. Females in the current study have a slightly higher SAD (23.7 cm) in comparison to female Middle Eastern immigrants in Sweden (22 cm) (Petersson et al. 2007). Amongst Asian Indians SAD was found to be significantly higher among diabetics (22.6 vs. 21 cm) (Anjana et al. 2004). The SADs reported in the current study are however higher comparison to Indians.

The mean values of WHR were 0.90 for the total sample, which is similar to the mean values of WHR in the Middle Eastern region (0.92) (Musaiger 2011). Males had a significantly higher WHR ($p < 0.001$) in comparison to females, 0.94 compared to 0.85 respectively. Neighbouring countries in the gulf region such as Oman, report similar findings. The mean WHR in Omani adults is 0.91, and females have a significantly lower WHR in comparison to males across different age groups (Al-Riyami and Afifi 2003). The WHR of US adults (0.90) is comparable to this study sample (Li et al. 2010). However, Saudi adults have higher WHR when compared to other countries in the Middle East, the WHR of Iraqi females is 0.81 (Al-Tawil et al. 2007), 0.92 in Palestinian males, and 0.81 for females (Abdul-Rahim et al. 2001). Africans have a lower WHR (0.84 for males, 0.80 for females) in comparison to Saudi adults (Okosun et al. 1998). When comparing to the WHO cut-offs for metabolic risk (≥ 0.90 for males, ≥ 0.85 cm for females), Saudi adults may have a substantially increased risk for metabolic disorders (WHO 2011). Adults with diabetes had a significantly higher WHR in

comparison to NDM in both females (0.89 vs. 0.83) and males (0.97 vs. 0.92), these observations are comparable to US diabetic populations (Li et al. 2010).

Socio-demographic characteristics varied significantly across diabetes groups in both females and males. The highest marriage rate was among females and males with prevalent diabetes, while the highest prevalence of being single was amongst non-diabetics. Western studies report different findings, the Whitehall II study found no association between marital status and diabetes incidence (Kumari et al. 2004), whilst in the US marriage was associated with a higher diabetes prevalence amongst women (Beckles et al. 2001). There is no previous evidence on marital status and the prevalence of diabetes in Saudi Arabia, however, local observational studies have shown a positive association between marriage and diabetes risk factors (Al-Nozha et al. 2007, Al-Baghli et al. 2008). In other areas in the Middle East such as Oman, one study has shown an association between marriage and the risk of diabetes in 7179 adults (Al-Moosa et al. 2006), and the same has been observed in Iranian adults (Rahmanian et al.), whilst married Syrian adults have reported lower self-rated health (Albache et al. 2010).

There was no significant difference in consanguinity and consanguinity degree across groups. Females with T2DM reported the highest consanguineous marriages (64.4%) and 57.3% married a first cousin. The overall prevalence of consanguineous marriages in Saudi Arabia is 56%, and marrying a first cousin is the most frequent among all marriages (33.6%) (Middle 2007). In Riyadh, around 40% of marriages are to a first degree cousin, and the prevalence of consanguineous marriages is similar to other Middle Eastern countries (El-Hazmi et al. 1995). It has been suggested that consanguinity may play a role in the prevalence of T2DM, but this has not yet been confirmed within the Saudi context (Elhadd et al. 2007, Al-Daghri et al. 2011). In

Bahrain, there was no association between consanguinity and the prevalence of T2DM (Al-Mahroos and McKeigue 1998).

Family history of diabetes has been recognized as significant risk factor for diabetes, and is considered an important predictor for diabetes (Harrison et al. 2003, Lindström and Tuomilehto 2003). The findings of the current study showed that reports on first-degree family history of diabetes were the highest in all groups. Over half of participants with prevalent diabetes reported a first-degree family history of diabetes. In this study, the prevalence of family history of diabetes is generally higher than neighboring countries. For instance, in 3307 Iranian adults only 27% had a positive family history of diabetes (Harati et al. 2009). In Qatar, 30.1% of diabetes cases reported a positive family history (Bener et al. 2009). In the NHANES 1999–2002 survey, US adults with diabetes reported higher figures of first-degree family history of diabetes (61.5%) in comparison to non-diabetics (27%) (Annis et al. 2005). In subsample of the EPIC cohort, around 9% of participants with prevalent diabetes reported a first-degree history (Sargeant et al. 2000).

Education levels varied significantly across groups, where illiteracy was higher amongst diabetics, and reports of higher education were higher in males with no diabetes 36.2% in comparison to 19.5% in T2DM. Although males with diabetes reported a higher annual income, there was no significant difference across groups. Lower education, unemployment status and lower income are traditional risk factors for T2DM in Western societies (Tang et al. 2003, Krishnan et al. 2010, Lee et al. 2011); these factors may play a different role in a country such as Saudi Arabia, which is undergoing a rapid epidemiological and nutritional transition. Earlier observations have shown that higher income is associated with a higher prevalence of diabetes (Fatani et al. 1987) and

diabetes risk factors in Saudi adults (Alsaif et al. 2002). Saudi Arabia is considered a rich country and individual's annual income has increased significantly over the years. Lower awareness and increased disposable income has played a major role in the adoption of unhealthy lifestyle behaviors that may have increased the prevalence of T2DM (Al- Khader 2001, Boutayeb et al. 2012).

Reports on smoking did not differ across groups, however, the prevalence of former smokers was higher amongst males with diabetes, and current smoking was lower amongst diabetics. The duration of quitting smoking was significantly higher amongst diabetics, which may indicate that diabetics quit smoking because of their condition. Underreporting in females was extremely high; this may be due to the cultural and social stigma associated with smoking amongst Saudi females (Bassiony 2009).

Physical inactivity was significantly higher in males with diabetes (34.9%) compared to non-diabetics (21.3% $p < 0.001$). Although participants, diabetics and non diabetics, reported physically activity, when observing the intensity of physical activity, the majority reported mild levels of physical activity (e.g. washing dishes) and the minority reported higher intensities. The prevalence of physical inactivity in Saudi Arabia is over 90%, and females are less active than males (Al-Nozha et al. 2007). In a cross-sectional survey which included 2176 PHCC's attendees, around 50% of the sample reported no performance of leisure activity (Amin et al. 2012). Another survey which included 1064 participants aimed to assess physical activity in adults living in Riyadh. The results showed that 43% of adults did not engage in moderate-intensity physical activity, whilst over 72% of Saudi's did not engage in any vigorous-intensity physical activity (Al-Hazzaa 2007). There are several reasons for such high rates of inactivity in Saudi Arabia; the rapid economic boost has increased the dependency on technological

inventions (e.g. cars), and hiring help for household work is affordable. The infrastructure, hot weather, and cultural restrictions do not encourage people to engage in outdoor activities, and because of poor public transportation, the dependency on cars is extremely high, where the number of cars is around 336 per 1000 individuals (Al-Hazzaa and Al- Rasheedi 2007, Al-Hazzaa 2007, Al-Nozha et al. 2007, Amin et al. 2012).

Numerous epidemiological studies have illustrated the association between sleep deprivation and cardiovascular disease (Shankar et al. 2010), hypertension (Mallon et al. 2005, Gangwisch et al. 2006, Cappuccio et al. 2007), obesity (Stranges et al. 2008, Shankar et al. 2010), poor wellbeing (Stranges et al. 2012), and diabetes (Mallon et al. 2005, Yaggi et al. 2006). The mean number of sleeping hours in the overall sample was 7.69 hours, and males reported significantly ($p = 0.005$) lower sleeping hours (7.62) in comparison to females (7.80). The sex difference is in line with previous Saudi observations (Alotair et al. 2008), US (Young et al. 1993) and Chinese populations (Li et al. 2002). Diabetics slept significantly less time than non-diabetics and pre-diabetics, and females with diabetes had higher reports of disrupted sleeping patterns (51.4%) in comparison to other groups. There is a lack of evidence in Saudi on the association between sleep duration and quality and diabetes. Shorter sleep duration has been associated with T2DM across several populations, mostly from developed countries (Yaggi et al. 2006, Cappuccio et al. 2010).

It is well established that chronic conditions, such as HTN and cardiovascular disease, are more prevalent in adults with diabetes (Kannel et al. 1979, Turner et al. 1998, Sowers et al. 2001). The overall prevalence of HTN was 24.4% in the overall sample. Blood pressure parameters were significantly higher in males in comparison to females,

which contributed to a significantly higher prevalence of HTN amongst males at 28.5% compared to 20.1% in females. There was a linear increase in both systolic and diastolic blood pressure, and the prevalence of HTN across diabetes groups, where prevalent diabetes cases had the highest prevalence of HTN (43.9% in females, 48.6% in males). The National Epidemiological Health Survey which included 17,230 Saudi adults (30-70 years of age) from different regions of the country reported similar findings. The overall prevalence was 26.1%, and a similarly significantly higher prevalence of HTN was seen in males (28.6%) in comparison to females (23.9%). The prevalence in the central region of Saudi Arabia was higher, at 30%, which may be attributed to the older age of the study sample in this region (Al-Nozha et al. 2007). Another cross-sectional survey in Riyadh included 9149 participants and reported an overall prevalence of HTN of 32.6% (Al-Daghri et al. 2011), however, the age of participants ranged from 7 to 80 years, which is not comparable to the current study's age range. Neighbouring countries report a higher prevalence of HTN, however, they report similar sex differences. The prevalence of HTN in 6414 Omani adults aged ≥ 20 years is 33.1% (Al-Riyami and Afifi 2003), and 31.7% in 1208 Qatari adults (25-65 years) where males had a slightly higher prevalence 32.6% in comparison to females 31.7% (Dagash et al. 2004).

The prevalence of HTN in the United Arab of Emirates (UAE) is 25.9%, and females with diabetes had a lower prevalence (39%) in comparison to T2DM males (42%) (Malik et al. 2005). The third national Surveillance of Risk Factors of Non-Communicable Diseases (SuRFNCD-2007) conducted in 5287 Iranian adults (15-64) reported an overall prevalence of 26.6%. In contrast to the current study, females had a higher prevalence (28.6%) in comparison to males (24.7%) (Esteghamati et al. 2009). Lebanon reported lower figures, the prevalence of HTN in Lebanese adults ($n = 2125$) aged 30 years or older is 23.1% (Tohme et al. 2005). Western countries report higher

rates in adults with similar age ranges to this study. The UK prevalence (41.7%) is much higher than Saudi, whilst the US and Canada figures are slightly higher (27.8%, 27% respectively) (Wolf-Maier et al. 2003) than Saudi.

Very few studies have assessed the prevalence of HTN in Saudi diabetics, and in the Gulf region in general (Alhyas et al. 2011). The largest cross-sectional survey, conducted in different regions of the Kingdom, included 14,805 Saudis. The prevalence of HTN in diabetics was 13.5%, and females with diabetes had a higher prevalence (15.9%) in comparison to males (11.4%) (El-Hazmi et al. 2001). It is difficult to compare the findings to the current study for several reasons. The study included different regions of Saudi whilst this study was based in Riyadh. The study sample included more females (58% vs. 42%) whilst in the current study it was the opposite. The age of participants ranged from 14-69, and the mean age of females was 27.3 years which is around 10 years younger than the current study population.

Lipid abnormalities are prevalent amongst Saudi adults, and are higher amongst males in comparison to females (Al-Kaabba et al. 2012). The prevalence of lipid abnormalities was high in the overall sample and across different groups, however, the prevalence was higher amongst diabetics. Mean levels of TG were similar to earlier surveys (Al-Nuaim et al. 1996, Al-Nozha et al. 2008). Recent local reports indicate that lipid abnormalities affect 90% of Saudi adults and that this is mainly derived by the extremely high prevalence of low levels of HDL-C (88.6%) (Al-Daghri et al. 2010). A similar observation was found in this study where the prevalence of lipid abnormalities was 93.9% in the overall sample and 71.2% of the participants had HDL-C <1.03 (data not shown). Reports on the prevalence of lipid abnormalities in the Gulf region have ranged between 2.7-51.9%, however, diagnostic methods are heterogeneous across studies

(Alhyas et al. 2011). Saudi adults with diabetes have similar TG levels to US diabetics (around 2.06 mmol/L) (Ghandehari et al. 2008).

Finally, it is well established that gestational diabetes mellitus (GDM) increases the risk of T2DM in females (Kim et al. 2002, Ben- Haroush et al. 2004, Buchanan et al. 2005). GDM affects 12.5% of pregnancies in Saudi, 20.6% in the UAE, 17.8% in India and around 17.8% in Canada (Bener et al. 2011). History of GDM has increased significantly across the three groups in this study, and 13.7% of females with diabetes have reported a history of GDM. Females with diabetes conceived at an earlier age in comparison to NDM and PDM ($p = 0.012$).

In summary, the descriptive analysis of the study sample has provided some insights of the demographic, social, anthropometric, and chronic conditions associated with diabetes in this study. Although diabetes is a prevalent condition in Saudi Arabia, and in the Middle East in general, there is a gap in the evidence on the risk factors associated with diabetes such as anthropometric measures, marital status, consanguineous marriages, sleeping patterns and other major lifestyle behaviors, reproductive characteristics in females, HTN and lipid abnormalities.

Summary

In this chapter the descriptive analysis of 2631 participants has been presented. Analysis was stratified by sex and diabetes status. In the next chapter (Chapter 8), analyses on the associations between dietary factors and T2DM will be presented. The first part will explore the association between anthropometric measures (BMI, WC, WHR, SAD) and T2DM, and will include the methods, results and discussion.

8 Dietary factors and T2DM: the role of anthropometric measures

Introduction

In this section the associations between anthropometric measures (BMI, WC, WHR, and SAD) and T2DM are presented for participants with no diabetes (NDM) and T2DM ($n = 2355$), with analyses stratified by sex. The aim was to use the Biomarkers Screening survey in Riyadh (2009) dataset to examine the associations of several measures of body weight and body fat distribution with the prevalence of T2DM in Saudi adults. Associations between T2DM and selected foods, beverages and micronutrient status are presented in chapters 9 and 10.

8.1. Methods

For this chapter, the sample included participants from the Biomarkers Screening Survey in Riyadh dataset with ($n = 770$) and without T2DM ($n = 1585$). Participants with T2DM were either previously diagnosed T2DM ($n = 488$) or newly diagnosed T2DM ($n = 282$). Differences between participants with newly diagnosed T2DM and previously diagnosed diabetes were observed for some of the anthropometric measures (Appendix 6). Sensitivity analyses were conducted to determine the effects of including previously diagnosed and newly diagnosed T2DM on the associations and the estimates

were found to be similar (Appendix 7). Therefore, for these analyses, both previously diagnosed and newly diagnosed T2DM were included (shown in figure 8.1.).

The dataset included weight (kg), height (cm), BMI (kg/m^2), waist circumference (cm), hip circumference (cm), and sagittal abdominal diameter (cm). Waist to hip ratio (WHR) was calculated by dividing the waist circumference by the hip circumference (WHO 2011). Further details on the collection of anthropometric measures are presented in “Chapter 6 – The biomarkers screening in Riyadh (2009) survey methods: 6.9. Anthropometric measures”. WHO BMI classifications were followed (WHO 2004) to be in line with the baseline BSR 2009 survey methods. There are no Saudi-specific cut-off points for WC, WHR, and SAD (Almajwal et al. 2009, Al-Daghri et al. 2010). Hence, the associations were examined across tertiles for each variable for the overall sample, and sex-specific tertiles in males and females separately. Sex stratification was set *a priori* because of the biological and social differences between females and males (Bird and Rieker 1999), as well as due to well-established differences in diabetes etiology and natural history between the two sexes (Donahue et al. 2007, Donahue et al. 2011). In addition, the descriptive characteristics of the study sample revealed significant differences in all anthropometric measures between females and males (presented in chapter 7).

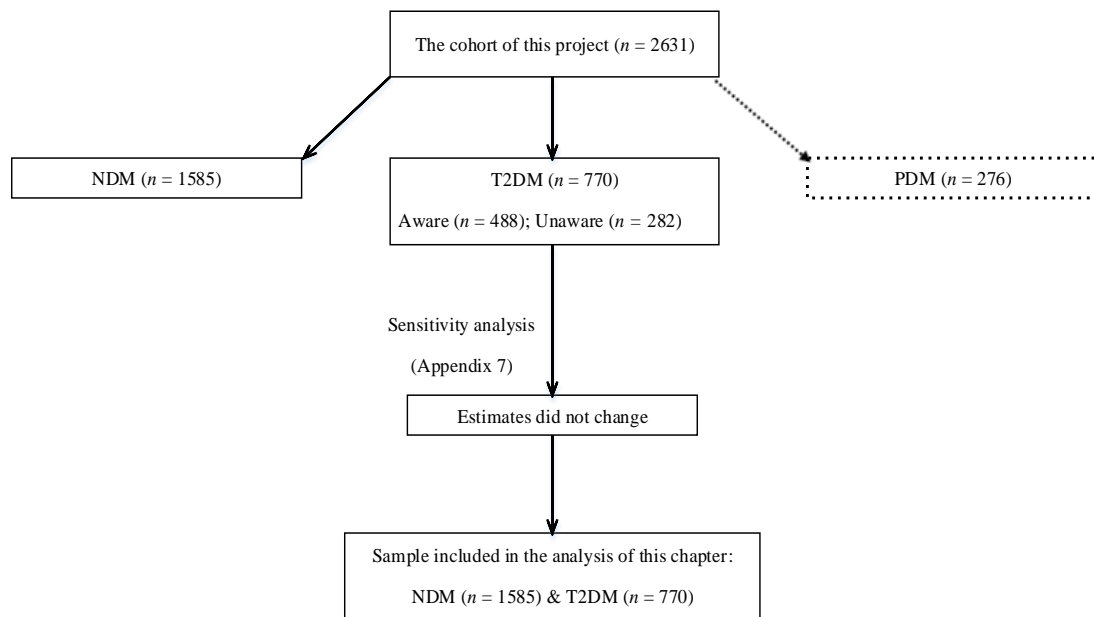


Figure 8.1. Selection of participants for the analysis of this chapter

8.2. Statistical analysis

Statistical analyses were conducted using the statistical package of social sciences SPSS Statistics V.21. Correlations between anthropometric measures were explored using the bivariate Pearson correlation test in the overall sample and in males and females separately. The outcome of this study was T2DM, therefore, logistic regression was used to calculate odds ratios (ORs) and 95% confidence intervals (CI) of T2DM prevalence across BMI groups and anthropometric measures tertiles. The lowest tertile was used as the reference category. The aim was to run a conservative model to minimise over adjustment, the selection of covariates was informed by the literature on the physiopathology and risk factor of T2DM (Chapter 3 – Literature review) and the descriptive characteristics of the overall sample (Chapter 7 – Descriptive characteristics of the 2631 participants of this project). For the overall sample, covariates included:

age, sex, socio-demographic variables (marital status, education level), family history of diabetes, lifestyle variables (physical activity, caloric intake from available dietary data). In sex-specific analyses, covariates included: age, socio-demographic variables (marital status, education level), family history of diabetes, lifestyle variables (physical activity, caloric intake from available dietary data), and history of gestational diabetes in the female group.

8.3. Results

A) Correlations between anthropometric measurements for the overall sample

Table 8.1. shows Pearson's correlation coefficients between anthropometric measurements of the overall sample ($n = 2355$). All anthropometric measurements correlated positively ($p < 0.001$), and the highest correlations were for BMI and WC ($r = 0.667$), followed by WHR and WC ($r = 0.496$), BMI and SAD ($r = 0.380$), WC and SAD ($r = 0.378$), and the lowest correlations were for WHR and BMI ($r = 0.137$). A similar trend was observed for BMI and WC correlations in both females and males (Table 8.2.), however, the correlations in females were consistently higher for BMI and WC ($r = 0.719$), WHR and WC ($r = 0.591$), WHR and SAD ($r = 0.258$) in comparison to males ($r = 0.700$, $r = 0.365$, $r = 0.214$ respectively).

Table 8.1. Pearson correlation coefficients between anthropometric measurements of the baseline sample

Variable	BMI (kg/m ²)	WC (cm)	WHR	SAD (cm)
BMI (kg/m ²)	1	0.667**	0.137**	0.380**
WC (cm)	0.667**	1	0.496**	0.378**
WHR	0.137**	0.496**	1	0.232**
SAD (cm)	0.380**	0.378**	0.232**	1

** $p < 0.001$ for all correlations

Table 8.2. Sex stratified correlations between anthropometric measurements

Females ($n = 1147$)

Variable	BMI (kg/m ²)	WC (cm)	WHR	SAD (cm)
BMI (kg/m ²)	1	0.719**	0.208**	0.344**
WC (cm)	0.719**	1	0.591**	0.359**
WHR	0.208**	0.591**	1	0.258**
SAD (cm)	0.344**	0.359**	0.258**	1

** $p < 0.001$ for all correlations

Males ($n = 1208$)

Variable	BMI (kg/m ²)	WC (cm)	WHR	SAD (cm)
BMI (kg/m ²)	1	0.700**	0.196**	0.446**
WC (cm)	0.700**	1	0.365**	0.403**
WHR	0.196**	0.365**	1	0.214**
SAD (cm)	0.446**	0.403**	0.214**	1

** $p < 0.001$ for all correlations

B) Odds ratio of T2DM prevalence by anthropometric measurements in the overall sample

Table 8.3. shows the ORs (95% confidence interval) for T2DM prevalence across tertiles of BMI, WC, WHR, and SAD for the overall sample. Both overweight and obesity were associated with T2DM, however, only obesity remained significantly associated with T2DM in fully-adjusted models. Compared with adults with normal weight, those with a BMI of 25-29.9 kg/m² had a significant increase ($p = 0.010$) in the odds ratio (OR 1.51, 95% CI, 1.1-2.0) for diagnosed diabetes after adjusting for age, sex and socio-demographic variables (Model 3). However, this association attenuated after further adjustments (Model 4 and 5). Adults with a BMI of ≥ 30 kg/m² had an OR of 2.08 (95% CI, 1.4-3.0, $p < 0.001$) for diagnosed diabetes in the fully adjusted model (Model 5). Adults with higher WC values had significantly higher ($p < 0.001$) ORs for diabetes in both the 2nd (OR 2.18, 95% CI, 1.5-3.1) and 3rd (OR 2.41, 95% CI, 1.6-3.4) tertiles of WC. Higher values of WHR were associated with diabetes, however, after further adjustments (Model 5) adults in the 2nd tertile had an OR of 1.41 (95% CI, 0.99-1.99) which was borderline significant ($p = 0.052$). Adults in the top tertile of WHR had an OR of 1.84 (95% CI, 1.2-2.6) where the association remained statistically significant after further adjustments ($p = 0.001$). Adults in the highest tertile of SAD (> 25.1 cm) had significantly higher OR of 1.71 (95% CI, 1.2-2.5) of diagnosed diabetes in comparison to adults with lower SAD (< 21.0 cm) OR of 1.17 (95% CI, 0.8-1.6).

Table 8.3. Odds ratio (95% CI) of T2DM prevalence by anthropometric measures of the overall sample

BMI (kg/m²)	18.5-24.9	25.0-29.9	≥30.0	p for trend
	(Normal)	(Overweight)	(Obese)	
Model 1	1.00	2.09 (1.6-2.7) **	2.86 (2.2-3.6) **	<0.001
Model 2	1.00	1.47 (1.1-2.0) *	2.28 (1.7-3.1) **	<0.001
Model 3	1.00	1.51 (1.1-2.1) *	2.27 (1.6-3.1) **	<0.001
Model 4	1.00	1.42 (0.9-2.1)	2.08 (1.4-3.0) **	<0.001
Model 5	1.00	1.39 (0.9-2.1)	2.08 (1.4-3.0) **	<0.001
WC (cm)	≤ 87.0	87.1-101.9	≥102	p for trend
	(I)	(II)	(III)	
Model 1	1.00	3.26 (2.5-4.2) **	4.84 (3.7-6.2) **	<0.001
Model 2	1.00	2.12 (1.5-2.8) **	2.76 (2.0-3.6) **	<0.001
Model 3	1.00	2.11 (1.5-2.8) **	2.72 (2.0-3.6) **	<0.001
Model 4	1.00	2.11 (1.4-2.9) **	2.36 (1.6-3.3) **	<0.001
Model 5	1.00	2.18 (1.5-3.1) **	2.41 (1.6-3.4) **	<0.001
WHR	< 0.85	0.85-0.94	> 0.94	p for trend
	(I)	(II)	(III)	
Model 1	1.00	2.37 (1.8-3.0) **	4.55 (3.5-5.8) **	<0.001
Model 2	1.00	1.55 (1.1-2.0) *	2.50 (1.8-3.3) **	<0.001
Model 3	1.00	1.53 (1.1-2.0) *	2.46 (1.8-3.3) **	<0.001
Model 4	1.00	1.42 (1.0-2.0) *	1.85 (1.2-2.6) *	<0.001
Model 5	1.00	1.41 (0.9 -1.9)	1.84 (1.2-2.6) *	<0.001
SAD (cm)	< 21.0	21.0-25.0	> 25.0	p for trend
	(I)	(II)	(III)	
Model 1	1.00	1.96 (1.5-2.5) **	2.81 (2.1-3.6) **	<0.001
Model 2	1.00	1.26 (0.9-1.6)	1.77 (1.3-2.3) **	<0.001
Model 3	1.00	1.22 (0.9-1.6)	1.79 (1.3-2.4) **	<0.001
Model 4	1.00	1.22 (0.8-1.7)	1.80 (1.2-2.5) *	0.001
Model 5	1.00	1.17 (0.8-1.6)	1.71 (1.2-2.5) *	0.001

** $p < 0.001$; * $p < 0.05$; **Model with summary:** Model 1. Unadjusted; Model 2. Adjusted for age and sex; Model 3. Adjusted as previous plus socio-demographic variables (marital status, education level) Model 4. Adjusted as previous plus family history of diabetes; Model 5. Adjusted as previous plus lifestyle variables (PA, log total KCAL).

C) Odds ratio of T2DM prevalence by anthropometric measurements - sex-stratified analyses

Table 8.4. shows the sex stratified odds ratios for diabetes by anthropometric measures. Obese females had an OR of 3.39 (95% CI, 1.5-7.6, $p = 0.001$) for diagnosed diabetes, whilst obese males had a borderline association with diabetes (OR 1.41, 95% CI, 0.8-2.2, $p = 0.077$). Higher values of WC were associated with diabetes in both females and males, however, this association attenuated in females after adjusting for history of GDM (Model 6). Nevertheless, males with a higher WC (≥ 104 cm) had a significant association with diabetes even after multivariate adjustment (OR 1.99, 95% CI, 1.2-3.1, $p = 0.006$). Females in the highest WHR tertile (≥ 0.91) had an OR of 1.73 (95% CI, 1.1-2.8, $p = 0.024$) for diagnosed diabetes, however, this association attenuated after adjusting for history of GDM. Males with higher values of WHR (≥ 0.97) had a statistically significant OR of 2.02 (95% CI, 1.2-3.1, $p = 0.001$) for diabetes. Males with increased SAD (≥ 26 cm) had a significant association with diabetes in the fully adjusted model (OR 1.79, 95% CI, 1.1-2.8, $p = 0.007$).

Table 8.4. Odds ratio (95% CI) of T2DM prevalence by anthropometric measures stratified by sex

Variable	Females (<i>n</i> = 1147)			<i>p</i> for	Males (<i>n</i> = 1208)			<i>p</i>
BMI	18.5-24.9	25.0-29.9	≥30.0	trend	18.5-24.9	25.0-29.9	≥30.0	for trend
(kg/m ²)	(Normal)	(Overweight)	(Obese)		(Normal)	(Overweight)	(Obese)	
Model1	1.00	2.98 (1.8-4.9)**	5.41 (3.3-8.6)**	<0.001	1.00	1.85 (1.3-2.5)**	2.20 (1.5-3.0)**	<0.001
Model2	1.00	1.61 (0.9-2.8)	2.73 (1.5-4.6)**	<0.001	1.00	1.39 (0.97-2.0)	1.93 (1.3-2.7)**	<0.001
Model3	1.00	1.48 (0.8-2.6)	2.46 (1.4-4.2)**	<0.001	1.00	1.50 (1.0-2.2)*	2.00 (1.3-2.9)**	<0.001
Model4	1.00	2.41 (1.1-5.0)*	3.54 (1.7-7.1)**	<0.001	1.00	1.06 (0.6-1.7)	1.47 (0.9-2.3)	0.057
Model5	1.00	2.47 (1.1-5.2)*	3.68 (1.8-7.4)**	<0.001	1.00	1.00 (0.6-1.6)	1.41 (0.8-2.2)	0.077
Model6	1.00	2.26 (0.9-5.3)	3.39 (1.5-7.6)*	0.001	NA	NA	NA	
WC (cm)	≤ 84.30	84.31-97.1	≥98.0	<i>p</i> for	≤ 90.0	90.1-103	≥104	<i>p</i>
	(I)	(II)	(III)	trend				for trend
Model1	1.00	3.81 (2.5-5.7)**	5.93 (3.9-8.9)*	<0.001	1.00	2.57 (1.8-3.5)**	3.45 (2.4-4.7)**	<0.001
Model2	1.00	2.07 (1.3-3.2)*	2.50 (1.5-3.9)*	<0.001	1.00	1.93 (1.3-2.7)*	2.43 (1.6-3.4)*	<0.001
Model3	1.00	1.97 (1.2-3.1)*	2.36 (1.4-3.7)*	<0.001	1.00	1.95 (1.3-2.8)*	2.42 (1.6-3.5)**	<0.001
Model4	1.00	1.93 (1.1-3.2)*	2.18 (1.3-3.6)*	0.005	1.00	1.71 (1.1-2.7)*	1.99 (1.2-3.1)*	0.005
Model5	1.00	2.02 (1.1-3.4)*	2.19 (1.2-3.7)*	0.007	1.00	1.72 (1.1-2.7)*	1.99 (1.2-3.1)*	0.006
Model6	1.00	1.53 (0.8-2.7)	1.59 (0.8-2.8)	0.161	NA	NA	NA	
WHR	<0.81	0.81-0.90	≥ 0.91	<i>p</i> for	≤0.90	0.91-0.97	≥ 0.97	<i>p</i>
	(I)	(II)	(III)	trend				for trend
Model1	1.00	1.91 (1.2-2.8)*	4.11 (2.8-5.9)**	<0.001	1.00	2.02 (1.4-2.8)*	4.01 (2.8-5.5)**	<0.001
Model2	1.00	1.14 (0.7-1.7)	2.13 (1.4-3.2)**	<0.001	1.00	1.29 (0.8-1.8)	2.60 (1.8-3.7)**	<0.001
Model3	1.00	1.11 (0.7-1.7)	2.16 (1.4-3.3)**	<0.001	1.00	1.41 (0.9-2.0)	2.66 (1.8-3.8)**	<0.001
Model4	1.00	1.21 (0.7-2.0)	1.78 (1.1-2.8)*	0.016	1.00	0.95 (0.6-1.5)	1.97 (1.2-3.0)*	0.001

Model5	1.00	1.15 (0.6-1.9)	1.73 (1.1-2.8)*	0.024	1.00	0.96 (0.6-1.5)	2.02 (1.2-3.1)*	0.001
Model6	1.00	0.97 (0.5-1.7)	1.38 (0.8-2.4)	0.207	NA	NA	NA	
SAD (cm)	≤ 20.0	20.1-24.9	≥ 25.0	<i>p</i> for	≤ 21.0	21.1-25.9	≥ 26.0	<i>p</i>
	(I)	(II)	(III)	trend	(I)	(II)	(III)	for trend
Model1	1.00	1.89 (1.2-2.8)*	2.39 (1.6-3.5)**	<0.001	1.00	1.47 (1.1-2.1)*	2.59 (1.8-3.5)**	<0.001
Model2	1.00	1.27 (0.8-2.0)	1.47 (0.9-2.2)	0.080	1.00	0.96 (0.6-1.4)	1.76 (1.2-2.5)*	0.001
Model3	1.00	1.30 (0.8- 2.1)	1.49 (0.9-2.3)	0.077	1.00	0.87 (0.5-1.3)	1.72 (1.1-2.4)*	0.002
Model4	1.00	1.23 (0.7-2.1)	1.44 (0.8-2.3)	0.150	1.00	0.92 (0.5-1.4)	1.77 (1.1-2.7)*	0.006
Model5	1.00	1.08 (0.6-1.9)	1.35 (0.8-2.2)	0.232	1.00	0.92 (0.5-1.5)	1.79 (1.1-2.8)*	0.007
Model6	1.00	1.00 (0.5-1.8)	1.15 (0.6-2.0)	0.603	NA	NA	NA	

** $p < 0.001$; * $p < 0.05$; **Model summery** Model 1. Unadjusted; Model 2. Adjusted as previous plus age; Model 3. Adjusted as previous plus socio-demographic variables (marital status, education level) Model 4. Adjusted as previous plus family history of diabetes; Model 5. Adjusted as previous plus lifestyle variables (PA, log total KCAL); Model 6. Adjusted as previous plus history of GDM (only in women).

The associations between relative weight, indicated by BMI, body fat distribution, indicated by WC, and T2DM in the overall sample were further examined, by using cross-classified tertiles of waist circumference and BMI groups. The age and sex adjusted association between T2DM and BMI attenuated within tertiles of WC (figure 8.2.). However, a direct and statistically significant association was observed between WC and the OR for diagnosed diabetes in the two highest BMI groups (figure 8.3.) in the overall sample. These results suggest that measures of central adiposity, such as WC, are associated with diabetes, independently of BMI, whereas the associations of BMI with diabetes is greatly attenuated after accounting for body fat distribution.

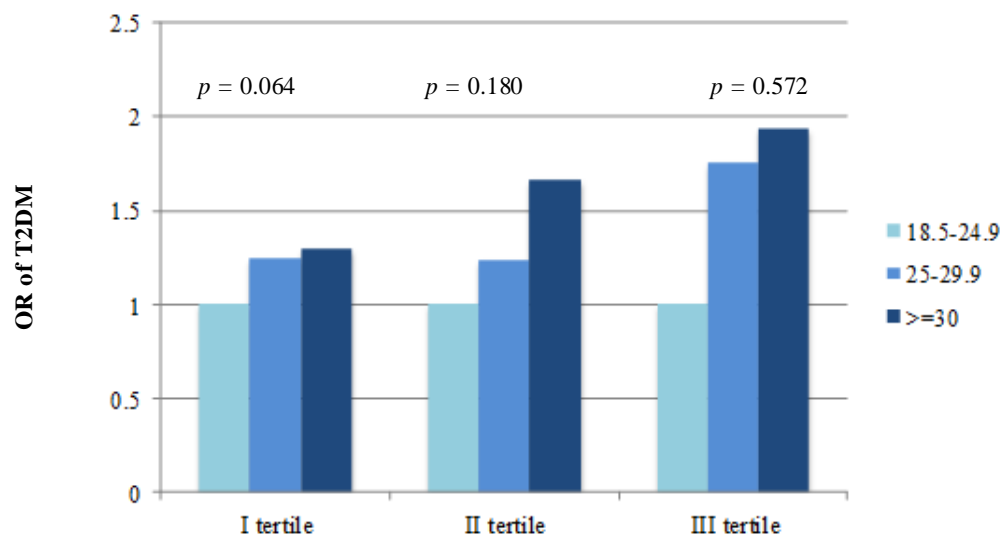


Figure 8.2. Age & sex adjusted OR for T2DM across BMI groups within each tertile of WC.

****p* values for linear trend across BMI groups within each tertile of WC**

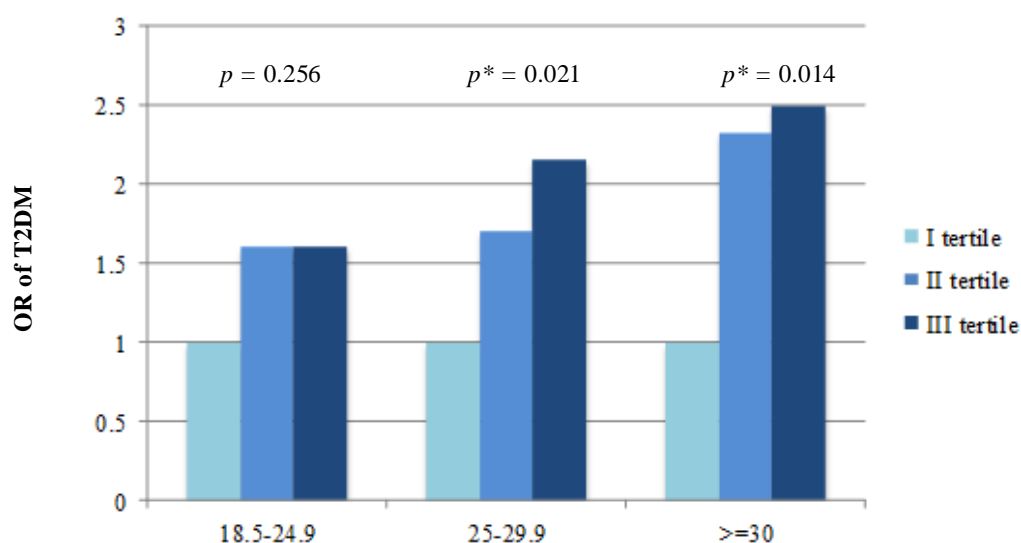


Figure 8.3. Age & sex adjusted OR for T2DM across tertiles of WC within each BMI group.
 **p* values for linear trend across tertiles of WC within each BMI group

8.4. Discussion

In this chapter the cross-sectional associations between anthropometric measures (BMI, WC, WHR, and SAD) and T2DM were presented for 2355 participants (NDM, T2DM) of the BSR dataset. The overall prevalence of obesity in this project was 41.2% (47.7% in females and 35.0% in males), which was significantly higher amongst diabetics (64.5% in females, 41.4% in males). WC, WHR, and SAD were high in the overall sample, and significantly higher amongst participants with T2DM. Adiposity is a major risk factor for T2DM, and is associated with diabetes markers (Despres 2006, Kahn et al. 2006). Saudi Arabia is in the top ten countries as to the prevalence of obesity (Badran et al. 2011), with an overall prevalence of 35.6% amongst Saudi Adults (Al-Nozha et al. 2005). Although overweight and obesity are a major health problem in Saudi Arabia, the associations between different anthropometric measures and T2DM

have not been extensively investigated within the Saudi context (El-Hazmi and Warsy 1999, Balkau et al. 2007, Elhadd et al. 2007, Musaiger 2011).

In this study, inter-correlations amongst BMI, WC, WHR, and SAD were strong and statistically significant ($p < 0.001$) in the total sample, and in both sexes. BMI and WC showed the highest correlation ($r = 0.667$), and were stronger amongst females in comparison to males. The findings are in line with earlier observations which have reported strong correlations between BMI and WC (Wei et al. 1997, Tulloch-Reid et al. 2003, Mukudde-m-Petersen et al. 2006). All anthropometric measures were significantly associated with T2DM in the fully adjusted model. In the overall sample, the highest association was observed for WC (OR 2.41, 95% CI, 1.69-3.44), followed by BMI (OR 2.08, 95% CI 1.4-3.0), then WHR (OR 1.84, 95% CI, 1.28-2.65), and finally SAD (OR 1.71, 95% CI, 1.24-2.54).

Observational studies from neighbouring countries have reported similar associations between T2DM and different anthropometric measures. Higher BMI (≥ 30 kg/m²) was significantly associated with T2DM in Kuwaiti adults (OR 1.46, 95% CI, 1.04-2.04) (Abdella et al. 1998). In Iran, various anthropometric measures were investigated, such as WC (Bozorgmanesh et al. 2011), BMI (Sadeghi et al. 2007, Harati et al. 2009) and WHR (Sadeghi et al. 2007, Hadaegh et al. 2009); all showed statistically significant associations with T2DM. However, some other Middle Eastern studies have found that WC may be the strongest predictor of T2DM (Al-Asfoor et al. 1999, Onat et al. 2006, Hadaegh et al. 2007), whilst others suggest that WHR is a stronger predictor of T2DM (Satman et al. 2002, Mansour et al. 2007, Mansour et al. 2007). Nevertheless, the

current evidence originates from a few countries in the Middle East, mainly Iran, and there is a lack of studies conducted in Saudi Arabia.

In the overall sample, the results suggest that different anthropometric measures are all significantly associated with T2DM in Saudi adults. These findings are also in line with international studies. For example, the prospective study by Wei *et al.* found that different anthropometric measures predicted T2DM, however, WC was found to be the strongest predictor in Mexican Americans (Wei *et al.* 1997). The Health Professionals Follow-Up Study from the US found that both BMI and WC were both good predictors for T2DM, whilst WC was a stronger predictor than WHR in men (Wang *et al.* 2005). The Hoorn study reported an increased risk of diabetes with increased WC (Snijder *et al.* 2003). Similarly, central adiposity, assessed by WC and SAD, was strongly associated with T2DM in Asian populations (Anjana *et al.* 2004). The Nurses' Health study from the US found that each anthropometric measure (BMI, WC, and WHR) was an independent predictor of T2DM (Carey *et al.* 1997). This was further confirmed by a meta-analysis, in which obesity measures (BMI, WC, WHR) showed similar associations with the pooled risk of diabetes (Vazquez *et al.* 2007).

The sex specific associations were explored in the current study, and results showed that BMI ($\geq 30 \text{ kg/m}^2$) remained significantly associated with T2DM in females in the fully adjusted model, whilst this association attenuated in males. The prevalence of obesity was significantly higher in females in comparison to males which may explain this strong association (OR 3.39, 95% CI, 1.5-7.6, $p = 0.001$). BMI has also been found to be significantly associated with T2DM in

Iranian women, and WC showed a significant association with T2DM (OR 3.1, 95% CI, 1.1-8.3, $p = 0.04$) (Hadaegh et al. 2009). The Iranian study included a larger number of females participants ($n = 2801$) and the reported association maybe driven by other covariates (socio-demographics, lifestyle, and female risk factors) which were not adjusted for in this study (Hadaegh et al. 2009). A recent cross-sectional study which included 4989 Iranian females, aged ≥ 20 years, has reported a significant association between BMI and the prevalence of diabetes (Bozorgmanesh et al. 2010). The Turkish Diabetes Epidemiology Study reported a significant association between BMI, WHR and diabetes in women aged ≥ 20 years (Satman et al. 2002). The results of the current study are similar to international populations. For example, BMI was strongly associated with diabetes in US women (Weinstein et al. 2004). In Australian adults, the age-adjusted association between BMI and diabetes was stronger in females in comparison to males (Dalton et al. 2003). In another investigation from the Nurses' Health Study in the US, overweight and obesity were the most important predictors of diabetes in adult women (Hu et al. 2001).

The Health Professionals Follow-up study from the US found that both BMI and WC were similar predictors to T2DM in males (Wang et al. 2005). In Pima Indians BMI was found to be a strong predictor of T2DM in males (Tulloch-Reid et al. 2003). However, this may not be the case in Saudi men, where central adiposity measures remained significantly associated with T2DM whilst the association attenuated for BMI. In males, higher WC, WHR, and SAD were all similarly associated with diabetes in the fully adjusted model. Neighbouring countries report conflicting evidence. For example, BMI has been significantly

associated with diabetes prevalence in Iranian men, whilst WHR showed no significant association (Bozorgmanesh et al. 2010). On the other hand, both BMI and WHR was significantly associated with diabetes in Turkish men (Satman et al. 2002), whilst in Bahraini adults, central adiposity indicated by WC was strongly associated with T2DM (Al-Mahroos and McKeigue 1998). The results of this study are similar to Korean populations, where only WC was associated with T2DM in men (Paek et al. 2010). In the San Antonio Heart Study, WC was the best predictor of type 2 diabetes compared with other measures in 25–64 year old Mexican Americans (Wei et al. 1997). Similarly, the Atherosclerosis Risk in Communities (ARIC) cohort found that WC was a strong predictor for diabetes in African American and white adults (Stevens et al. 2001), whilst in Chinese populations both general obesity and central adiposity were similarly associated with diabetes (Jia et al. 2011).

In the overall sample, a direct and statistically significant association between the age-sex adjusted OR for diabetes and WC persisted within each group of BMI. However, this association was not significant between BMI and diabetes across tertiles of WC. Therefore, these results suggest that WC, a measure of central adiposity, is a much stronger correlate of diabetes than BMI, a measure of relative weight in this study. Moreover, the associations of central adiposity, indicated by WC, with diabetes were independent of BMI, whereas the opposite was not true. Researchers have concluded that abdominal fat localization often indicated by waist measure was more important than total body fat in predicting T2DM (Chan et al. 1994, Wei et al. 1997, Okosun et al. 1998). These findings

are applicable to Saudi populations, especially men, whilst relative weight seems to play a stronger role in Saudi women.

Summary

In this chapter the first section on the associations between surrogate markers of nutritional status, such as anthropometric measures, and T2DM were presented. Analysis was presented for the overall sample and stratified by sex. In the next chapter (Chapter 9), the second set of analyses on the associations between selected dietary factors and T2DM will be presented. The first section will cover the validation of the FFQ, and the second section will cover associations between selected foods and beverages and T2DM.

9 Dietary factors and T2DM: calibration study and association of selected food items with T2DM

Introduction

This chapter consists of two sections; the methods, results and discussion are presented for each section separately. In the first section, the calibration of the food frequency questionnaire (FFQ) is presented for a subsample ($n = 98$) from the original Biomarkers Screening in Riyadh cohort ($n = 2631$). In the second section, the associations between dietary variables (selected food and beverage items) and T2DM are presented for participants classified in two categories: those with newly diagnosed diabetes and those with no diabetes ($n = 1867$) from the original Biomarkers Screening in Riyadh cohort ($n = 2631$), with analyses stratified by sex.

Summary

In this section, the introduction to chapter 9 was presented. In the next section (Chapter 9 – section 1) the calibration study of the FFQ against two 24 hour recalls will be presented.

Section 1 Calibration of the food frequency questionnaire against two 24-hour dietary recalls

9.1.1. Methods

A) Study setting

The calibration study of the FFQ was conducted in six primary health care centres (PHCCs) in Riyadh, Saudi Arabia (Table 9.1). The PHCCs participated in the BSR survey in 2009. The choice of the six PHCCs was based on research nurse's availability, research costs, data collection time, and transportation.

Table 9.1. Participating PHCCs in the current study

PHCC	Location	<i>n</i>
Al Fawaz	West-eastern province	32
Al Marwa	West-eastern province	92
Ghubairah	Central	19
Iskan Al Maathar	Central	24
Al Badiyah	Southern province	97
Al Naseem Al Shargi	Eastern province	81
		Total 345

B) Ethical approval

Saudi ethical approval was obtained from the Ethics Committee of the College of Medicine Research Centre, King Saud University, Riyadh, KSA (available in Appendix 8). UK ethical approval was obtained from the Biomedical Research Ethics Committee of the University of Warwick (available in Appendix 9).

C) Dietary assessment methods

Nutritional tools such as the FFQ, which was used in the original BSR survey (2009), require validation to report accurate estimates of dietary intake (Margets et al. 1997, Willett 1998, Subar et al. 2001). In order to validate a dietary measurement tool (FFQ in this study), a standard reference tool is required to be compared to the dietary measurement tool, also known as the “test tool” (the FFQ in this study) (Margets and Nelson 1997, Willett 1998, Cade et al. 2002). In the validation of a FFQ, there is no self-reported “gold standard” tool (reference tool) for comparison (Subar et al. 2001).

D) Rationale behind the choice of the reference tool (24-hour dietary recall)

Recovery biomarkers, nearly unbiased measures of dietary intake as they are not subject to large inter-individual differences in metabolism, such as doubly labelled water (to measure energy expenditure) and 24-hour urine (to measure sodium, potassium and protein) have the greatest appeal as the “gold standard” in

assessing the validity of a measurement tool (test tool) (Coulston et al. 2008, Freedman et al. 2010). However, these biomarkers are available for only certain dietary variables (as mentioned above) and are extremely expensive (Coulston and Boushey 2008) which made it impractical to use in the current study.

Other independent “reference” dietary tools, such as diet records and 24-hour dietary recall, have been widely used in validation studies (Willett et al. 1987, Feskanich et al. 1993, Martin-Moreno et al. 1993, Decarli et al. 1996, Boeing et al. 1997, Kroke et al. 1999, Resnicow et al. 2000). However, the diet record requires weighing food, high literacy, cooperation and is time consuming (Willett 1988, Margets and Nelson 1997). Therefore, the 24-hour recall was considered the most practical “reference” tool for this study given the following limitations of the food record:

1. Time constraints: the Ministry of Higher Education in Saudi Arabia (the funding body for this project) allowed only three months for data collection. In addition, the diet record method requires training participants on how to complete a food record and that was not feasible within the time frame given.
2. Additional costs: the food record method requires the use of measurement tools (scales, electronic devices, household measures) which would have added additional costs to this project and these additional resources were not available.
3. Literacy: the food record method requires a high degree of literacy and that would have reduced the number of potentially eligible participants.

The 24-hour dietary recall requires less time, does not require high levels of literacy or cooperation (Willett 1998). Therefore the 24-hour dietary recall was chosen as a reference tool for the validation of the FFQ in the current project.

E) Food frequency questionnaire structure

The food frequency questionnaire used in the current study is a semi-quantitative questionnaire which assessed four dietary groups (Appendix 10). The choice of dietary items included in the questionnaire was previously mentioned in “Chapter 6 – The Biomarkers Screening in Riyadh (2009) Survey Methods: Dietary measurements preparation and cleaning”. The questions cover the amount of intake (portion), frequency of intake (weekly or daily basis), and type of food consumed (e.g. brown bread, white bread). The 17 dietary items (apple, pear, orange, banana, dates, egg, milk, sugar/honey, brown bread shami, white bread shami, regular brown bread, regular white bread, brown toast, white toast, shaboora, tea and coffee) were grouped into five categories: bread and bakery, egg and milk, fruits, dates, beverages (included questions on added sugar and sugar/honey). The structure of the questions was identical to the questions administered in the BSR survey (2009), and the questionnaire was in the Arabic language.

F) 24-hour dietary recall structure

The 24-hr dietary recall tool collects diet information on food and beverages which were consumed from midnight to midnight in the previous 24 hours

(Willett 1998, Thompson et al. 2009). This method requires a trained interviewer to obtain detailed dietary information from participants. The interview usually takes 20 minutes depending on the dietary data required from the participant (Willett 1998).

The five steps of Multiple-Pass Method (MPM) is a method that is recommended in collecting dietary data using the 24-hour dietary recall. This method consists of five steps using memory cues to ensure recall of all possible foods and beverages consumed in the past 24 hours. The MPM method focuses on five domains during an interview: quick list of the food consumed, forgotten/missed foods, time/occasion of food consumed, full details of the food reported and final review of the diet reported (Subar et al. 2001). The structure of the 24-hour recall (available in Appendix 11) was adopted from the EPIC-Norfolk 24-hour recall (EPIC) and the multiple pass method (Subar et al. 2001). The 24-hour recall was in the Arabic language and included four domains: a quick list of the foods/drinks consumed in the previous day, time/occasion, detailed description of what was consumed, and amount consumed.

G) Number of recalls and which days

Usually, one recall may be adequate to estimate mean intakes of individuals in a dietary study. However, the purpose of collecting a 24-hour recall in this study was to serve as a reference tool in the process of validating the FFQ. Since the FFQ produces measurement error, it is recommended to collect more than one recall to adjust for measurement error in nutritional analyses (Willett 1988). Due

time constraints, practicality and feasibility of data collection, two 24-hour recalls were deemed to be sufficient for the purpose of this current study.

Since the type of days (weekend vs. weekdays) may affect dietary intake, balance of days was taken into account in the methods of this study (Willett 1998). A weekday and a weekend recall were collected from each consenting participant.

H) Sample size calculation

A specialist statistician at Warwick Medical School (Dr Peter Kimani) was consulted for the sample size calculation for the current study. For the calibration of a FFQ, we were interested in the correlation between responses given using the two methods to assess dietary intake (FFQ vs. 24-hour dietary recall). The correlation coefficient has a skewed distribution, therefore, Fisher's Z-transformation has to be applied to correlation coefficients so that the normal approximation used for the sample size calculation is adequate (Willett 1998).

Assuming that the true correlation would be $\rho = 0.3$ (a very conservative correlation) and that the 95% confidence intervals would range from 0.1 to 0.5 if this were the case. The required sample size to estimate the correlation coefficient with this precision is $n = 91$. If the hypothesised true correlation were different, say $\rho = 0.4$, but the required precision remained the same (i.e. a 95% CI from 0.2 to 0.6), then the required sample size would be slightly reduced ($n = 82$).

I) Selection of potential participants

In the choice of population for a calibration study, it is ideal for the subjects to be a random selection of the original sample, the so-called “random internal validation” (Willett 1998). Hence, the aim was to generate a random sample, stratified by sex and diabetes status, of 275 participants (assuming a low response rate of 40%) out of the 345 available participants in the six PHCCs. Research nurses were contacted before data collection to discuss the feasibility of the proposed selection criteria. However, it was not possible to select participants on this basis due to missing/changed contact details. Therefore, the 345 participants were all selected for this current study. The serial numbers of the 345 participants in the six PHCCs were sent to research nurse’s prior to data collection.

Inclusion criteria

- Adults (aged ≥ 18 years) from both sexes, who participated in the BRP baseline survey 2009.
- Able to consent.
- Registered at the participating PHCC’s.
- Available contact details.

Exclusion criteria

- Pregnant or lactating women because they are more likely to change their usual dietary habits (al-Kanhal et al. 1995).

- Participants following a weight reduction diet as they are changing their usual eating habits.
- Unable to consent.

J) Invitation of potential participants

A flow diagram of the study design is available in figure 9.1. Six research nurses working at the PHCCs (Table 9.1.) who deliver care to participants of the original BSR survey (2009) invited participants through telephone calls. Telephone calls are the communication method used between PHCC's and registered citizens at their local centre. The serial number of the 345 participants was given to the nurses to invite participants to their local PHCC. Nurses reviewed the serial number of potential participants and identified available contact details. Nurses explained the objectives of the study over the phone, and participants who were happy to join were invited to their local PHCC's to provide written consent and initiate the interview.

K) Incentives

Participants who agreed to join the study were offered a free blood glucose check using a glucometer. Beverages and snacks were also offered to participants and to whoever accompanied them following the interview. Participants who completed the study were offered a free nutrition consultation for themselves and their family members.

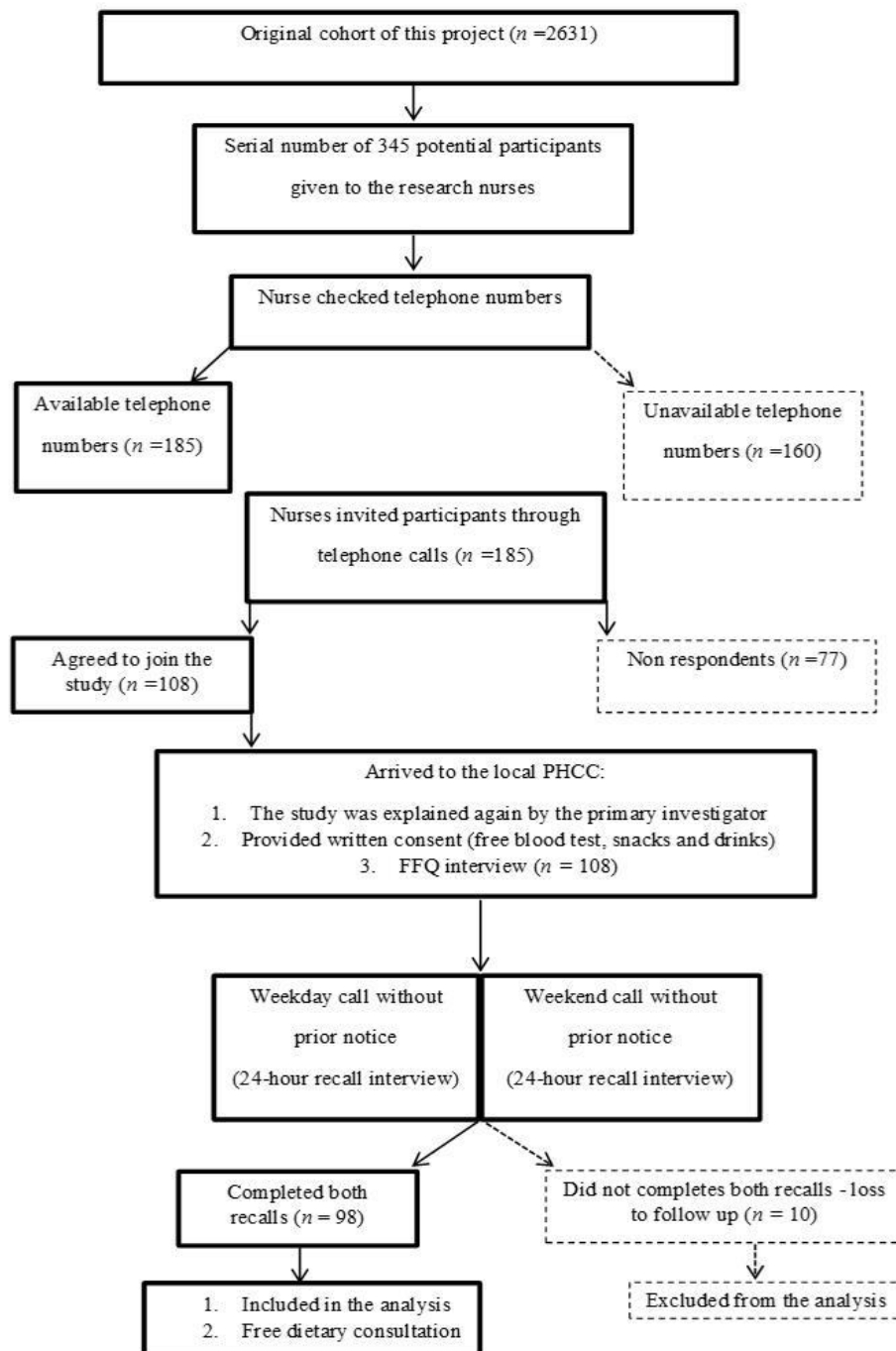


Figure 9.1. Flow chart of the FFQ calibration study

L) Mode of administration

Participants who agreed to join the study over the phone arrived to their local PHCC. At the PHCC, the primary investigator explained the aims for a second time to ensure that participants were fully aware of the study objectives and answered any questions raised by the participants. Participants who agreed to join the study then provided written consent and were interviewed.

M) Sequence of questionnaire administration

Firstly, we administered the FFQ ‘test tool’ followed by the 24-hour dietary recall ‘reference tool’ to decrease individual recall bias, as participants may be more aware of their diet when administering the ‘reference’ tool first (Willett 1998).

N) The FFQ interview

Face to face interviews were carried out at the PHCC by the primary investigator who completed the questionnaire. The interviewer, a clinical dietician, did not express in voice tone, facial expression or movement any approval or disapproval of reported answers by the participant. The FFQ interview lasted around 15-20 minutes. Participants were informed that they would be contacted (without prior notice) to complete a 24-hour dietary recall interview over the phone.

O) 24-hour dietary recall interview

After ten days of the FFQ interview, the 24-hour recall was completed through a telephone interview. Since two recalls were required for this study, telephone interview was the most appropriate and feasible method to reduce the burden of travelling on participants. Each participant was contacted twice, once on a weekday and once on a weekend. Participants were contacted at an early time of the day, 7:30 am and onwards to increase recall memory. Telephone calls were made without prior notice of the day of the call to ensure that participants would not alter their dietary intake in the previous day (Willett 1998). If the participant did not have a typical day (e.g. fasting) of eating habits in the previous day, the interviewer called on another day. Participants were asked about their dietary intake in the previous day using the five steps of the multiple pass method (Subar et al. 2001).

Phone call structure

- Greeting the participant.
- The interviewer introduced herself and explained the reason behind the phone call.
- Confirmed if the time was suitable for an interview, if not the interviewer called at another time/day.
- The interviewer asked if the previous day was a typical day of eating habits (e.g. no fasting). If yes, the interviewer began the interview, and if not the interviewer called on another day.
- Initiating the recall: 'I am going to ask you about everything you ate and drank yesterday. Yesterday means the 24 hours from midnight to

midnight. I would like to know exactly what you ate and drank and how much you had’.

First step: The interviewer started with the quick list of what the participant consumed the day prior the phone call. The respondent provided a quick list of what was eaten and drank yesterday without any interruption from the interviewer.

Second step: The interviewer asked about any forgotten food that people usually miss, *‘In addition to what you have told me, did you have the following items (e.g. tea, coffee)?’*

Third step: The interviewer went back to the quick list of the reported food items and asked about the time and occasion. *‘Was the (food/drink) the first thing you had yesterday?’* If the answer was yes, the interviewer moved to the **fourth step**, if not the interviewer would ask *‘So what was the first thing you had yesterday?’*.

Fourth step: A detailed record was obtained of the food items assessed by the FFQ in the current study (to reduce recall burden on the participants), *‘Now I would like to go through some of the foods/drinks you mentioned and ask you in detail about some of them’*. A detailed record would include description of the foods consumed such as portion size, type of food, preparation method and amount.

Fifth step: A final opportunity to recall any missing foods, *'Let's see if I have everything that you mentioned. Would you like to remember anything else that you had to eat or drink yesterday that you have not already told me about'*. At this final stage the interviewer asked questions that encouraged the participants to recall forgotten foods/beverages, for instance *'did you eat or drink anything whilst preparing your meal/waiting for your meal?'* or *'between (occasion/time) and (occasion/time) did you eat or drink anything?'*.

Finally, the participant was thanked for the recall and informed that he/she would be contacted on another day. If this was the final interview, the interviewer offered a free nutritional consultation, education, and to be in touch for any future nutritional queries.

9.1.2. Analysis

A) Nutritional analysis

Participants who completed both 24-hour dietary recalls were included in the final statistical analysis of the FFQ calibration study.

The FFQ data

Primarily, all data were in paper form and Arabic language. Back translation was carried out by the primary investigator. Nutritional data were reviewed and

coded by the primary investigator. Each food item had a unique code that was manually entered in the pre-built FFQ (QBuilder V2.0 Tinuviel nutritional software). Each code matched the food/drink code of the QBuilder nutritional database. Nutritional analysis was conducted to obtain the mean values of macronutrients (e.g. calories) and then exported to SPSS Statistics V.21 for statistical analysis.

24-hour dietary recall data

Data were in paper form and Arabic language and back translation was carried out by the primary investigator. Nutritional data were reviewed and coded by the primary investigator. Data was entered in the WISP V3.0 Tinuviel software. Nutritional composition of Arabic foods (e.g. shami bread) were obtained from the Arab Food Analysis Programme V1.0 (2007), and The Arabic Encyclopedia of Food and Nutrition (Musaiger 2009). Arabic nutritional data were built in the software with unique identifying codes for each item.

Each recall (weekend/weekday) was entered separately, and then the two recalls were consolidated to compute the mean intake for both recalls. Nutritional analysis was conducted to compute macronutrient values, and then the data were exported to SPSS Statistics V.21. for further statistical analysis.

Conversion of intake to servings

The conversion of crude intake to serving size per day was carried out following the methods of Thompson *et al.* (Thompson et al. 2002). The nutritional data (grams and millilitres) of each participant were exported from the Tinuviel nutritional software to SPSS Statistics V.21 to convert to serving size per day.

Serving size of each food was obtained from the Food Dome dietary guidelines for Arab countries (Musaiger 2012). For example, if a respondent reported eating 90 grams of white Shami bread 4 times per week; this translated to 3 servings * 0.571 times per day, or 1.71 servings per day from white Shami bread. The servings of each group (i.e. white bread group, brown bread group) were summed to get the overall servings per day for each food group. For example, if a respondent reported 1 serving per day from white Shami bread, 0.5 serving per day from white bakery bread, 0.5 serving per day of white toast; this translated to 2 servings of white bakery per day.

B) Statistical analysis

Statistical analysis was carried out using SPSS Statistics V.21. For continuous variables, an independent sample t-test was carried out to detect differences between groups (respondents vs. non-respondents), ANOVA was carried out to detect differences across groups (respondents, non-respondents and original cohort). For categorical variables a chi square test was carried out to detect differences between groups. The level of agreement between the FFQ and 24-hour dietary recalls was assessed using Pearson correlation coefficients for crude

correlations. Skewed nutrients were either logarithmically or square root transformed to improve the distribution of dietary values.

Energy adjusted correlations between the 24-hour dietary recall and the FFQ were computed following the Residual method (Willett et al. 1986):

1. Residual model: $FFQ_0 = \beta_0 \text{ food residual} + \beta_1 \text{ calories}$

The residual of a food item is obtained from the regression of the food from the FFQ (i.e. β_{fruits}) on the total calories (β_1).

2. Pearson correlation between the mean of the two 24-hour recalls for each food and the residual coefficient of that specific nutrient.

Adjustment for measurement error (within person variance and between person variance) was computed following the deattenuation formula, the deattenuation was calculated as:

$$\rho \sqrt{1 + (\frac{\sigma_w^2}{n}) / \sigma_b^2} \text{ (Stram et al. 2000)}$$

where ρ is the crude (unadjusted) correlation (between the FFQ and 24-hour recalls), σ_w^2 is the within-person variance of the 24-hour recalls, n is the number of 24-hour recalls (two in this study), and σ_b^2 is the between person variance. σ_w^2 and σ_b^2 are computed from a variance component analysis of the within person and between person variability of the two 24-hour recalls.

9.1.3. Results

A) Response rate

The total number of potential participants registered at the six PHCCs was 345 participants. Only 185 participants had available contact details, whilst the remaining 160 had missing/unavailable contact details. Nurses contacted the 185 individuals, where 77 individuals were either not available (e.g. travelling), could not be interviewed (e.g. primary investigator could not access the males section at the PHCC, could not provide written consent), did not show up, refused to join or moved to a different area. A total of 108 participants agreed to join the study and provided written consent.

The response rate of the current study was therefore 58.37%, however, there was no significant difference for the general characteristics between respondents ($n = 108$) and non-respondents ($n = 77$) (see Table 9.2). Participants who completed both the FFQ and the two 24-hour dietary recalls were included in the final analysis ($n = 98$); therefore, 10 participants were lost to follow-up. Differences for descriptive characteristics of the respondents and non-respondents and the whole cohort are presented in Table 9.2. There was no statistically significant difference between the respondents and non-respondents for all descriptive characteristics. There was no significant difference between the original cohort of this project ($n = 2631$) and the invited participants for the calibration study for the majority of variables. However, a significant difference was observed for sex, LDL-C and HDL-C.

Table 9.2. Descriptive* characteristics of respondents, and non-respondents, and original cohort

Variable	Respondents	Non respondents	p^1	Original cohort	p^2
<i>n</i>	108	77		2631	
Age (yrs)	43.17±13.58	43.23±16.71	0.976	40.80±15.47	0.124
Sex (%)					
Female	23.1% (25)	19.5% (15)	0.550	48.7% (1280)	<0.001
Male	76.9% (83)	80.5% (62)		51.3% (1351)	
Weight (kg)	82.46±16.44	77.72±15.52	0.051	76.63±17.32	0.003
BMI (kg/m ²)	30.05±5.79	28.50±5.82	0.078	29.16±6.36	0.237
WC (cm)	97.52±16.36	95.21±15.23	0.345	94.11±15.83	0.090
WHR	0.91±0.11	0.92±0.11	0.351	0.90±0.12	0.211
SAD (cm)	24.52±9.18	22.92±8.31	0.240	23.90±8.19	0.449
Systolic (mmHg)	121.73±12.96	120.27±14.51	0.513	120.26±14.41	0.639
Diastolic (mmHg)	78.80±7.12	76.89±8.49	0.134	77.41±8.62	0.284
FPG (mmol/L)	6.36±1.40	6.70±1.60	0.387	6.89±3.62	0.415
Cholesterol (mmol/L)	5.00±0.86	4.89±1.20	0.484	5.08±1.21	0.306
TG (mmol/L)	2.71±1.41	2.48±1.35	0.067	1.75±1.12	0.181
LDL-cholesterol (mmol/L)	3.63±0.88	3.63±0.91	0.989	3.40±1.05	0.015
HDL-cholesterol (mmol/L)	0.51±0.18	0.57±0.21	0.073	0.86±0.34	<0.001
Free from HTN	83.3% (75)	80.3% (53)	0.626	75.6% (1713)	0.171
HTN	16.7% (15)	19.7% (13)		24.4% (553)	
NDM	50.9% (55)	62.3% (48)	0.613	60.2% (1585)	0.903
PDM	10.2% (11)	7.8% (6)		10.5% (276)	
T2DM	38.9% (42)	29.9% (23)		29.3% (770)	
Family history of diabetes					
No family history	11.8% (9)	15.0% (9)	0.177	17.5% (345)	0.266
1 st degree family history	55.3% (42)	45.0% (27)		44.9% (884)	
2 nd degree family history	9.2% (7)	21.7% (13)		14.1% (278)	
1 st & 2 nd degree family history	23.7% (18)	18.3% (11)		23.4% (461)	

*Percentage (*n*) or mean values ± SD

p^1 indicates the statistical significance for differences between respondents and nonrespondents; p^2 indicates the statistical significance for differences between the original sample of this project and respondents and non-respondents; **BMI** indicates body mass index; **WC** indicates waist circumference; **WHR** indicates waist to hip ratio; **SAD** indicates sagittal abdominal diameter in cm; **FPG** indicates fasting plasma glucose; **TG** indicated triglycerides; **HTN** indicates self-reported hypertension and/or use of HTN drugs or systolic ≥140 mmHg or diastolic ≥90 mmHg; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **PDM**: pre-diabetes (self-reported pre-diabetes and/or FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **T2DM**: type 2 diabetes mellitus (self-reported T2DM and/or FPG ≥7.0 mmol/L; ≥126 mg/dL); **Family history of diabetes**: 1st degree includes father, mother, siblings or children. 2nd degree includes uncle, aunt, grandparents or grandchildren.

B) Comparison of the FFQ with 24 hour recalls

Within the data collection period, from April to June 2012, 98 of 108 participants completed both the FFQ and the two 24 hour dietary recalls. Amongst adults who participated in this study, 23.1% were females and 76.9% were males, and the mean age was 43 years.

No statistically significant differences were found between the mean values estimated by the FFQ and the two 24 hour dietary recalls for white breads and brown breads. On the other hand, the FFQ overestimated the values of milk, fruits, dates, tea, coffee and sugar/honey (Table 9.3.). Analysis of the correlation between the values of servings estimated by the FFQ and those estimated by the average of the two 24-hour dietary recalls demonstrated statistically significant correlations for all dietary variables. The unadjusted correlation was the highest for coffee ($r = 0.612$) and the lowest for milk ($r = 0.302$).

All the values for the correlation coefficients tended to decrease after being adjusted for energy except for brown breads, dates and milk. However, the decrease did not affect the statistical significance of the level of agreement between the FFQ and the 24 hour recalls. Correction for within- to between-person variability increased all values of the correlation coefficients. Whereas the unadjusted value for white breads was $r = 0.480$, the corrected value was $r = 0.799$; for brown breads, the unadjusted value was $r = 0.542$ and the corrected value was $r = 0.678$. Relatively high values were observed for all food items, the de-attenuated correlation was the highest for eggs ($r = 0.815$) whilst the lowest

was for milk ($r = 0.416$). The ratio of the components of within-person to between-person variability is presented in table 8.4. The variance ratio ranged from 0.3 for dates to 10.6 for eggs.

Overall, the foods with the lowest corrected correlation coefficients tended to have less variance ratio (Table 9.4.), for instance dates had a low variance ratio (0.3), therefore the energy adjusted correlation increased from 0.528 to 0.575. This indicates that the ratio of within- to between-person variance for dates has more variation in consumption between individuals than within individuals, therefore the corrected correlation coefficient had only a slight effect. The same was observed for coffee and brown breads. Eggs had the highest variance ratio (10.6), therefore the correlation coefficient improved from 0.326 to 0.815.

Table 9.3. Correlations between the FFQ and the two 24-hour dietary recalls

Food item (serving/day)	FFQ intake \pm SD	24-hr recalls intake \pm SD	<i>p</i> for difference	Correlations coefficients		
				Crude <i>r</i>	Energy adjusted <i>r</i>	De-attenuated <i>r</i>
White bread ^{LG}	1.75 \pm 1.39	1.86 \pm 1.41	0.200	0.480**	0.470**	0.799
Brown bread ^{LG}	1.39 \pm 1.37	1.37 \pm 1.50	0.742	0.542**	0.564**	0.678
Egg ^{LG}	1.18 \pm 1.32	1.12 \pm 1.17	0.023	0.379**	0.326**	0.815
Fruits ^{LG}	1.43 \pm 1.20	1.24 \pm 1.22	<0.001	0.425**	0.387**	0.541
Dates ^{LG}	1.68 \pm 1.26	1.33 \pm 1.25	<0.001	0.521**	0.528**	0.575
Sugar/honey ^{LG}	2.23 \pm 1.37	1.72 \pm 1.33	<0.001	0.458**	0.369**	0.479
Milk	2.61 \pm 1.78	1.63 \pm 1.81	<0.001	0.302*	0.320**	0.416
Tea	5.64 \pm 3.95	3.59 \pm 2.41	0.006	0.583**	0.537**	0.698
Coffee	5.66 \pm 3.62	3.77 \pm 3.38	0.024	0.619**	0.612**	0.673
Calories (kcal/day) ^b	1208.49 \pm 501.21	1028.20 \pm 431.12	0.008	NA		

^{LG} variables were logarithmically transformed for normality; ^bCalories are the calories from the presented food items; ***p* \leq 0.001; **p* < 0.05; **Crude** indicates unadjusted simple Pearson's correlation coefficient; **Energy adjusted** indicates correlation adjusted for calorie intake following the residual method; **De-attenuated** indicates correlation adjusted for calorie intake following the residual method + measurement error.

Table 9.4. Variance components of the food intakes estimated by two 24 hour recalls

Food item	Variance ratio ^a	Within-person variance	Between-person variance
White bread	4.0	13.706429	3.387152
Brown bread	0.9	11.530155	11.720444
Egg	10.6	0.553024	0.052021
Milk	1.3	0.293586	0.211429
Fruits	2.2	1.088035	0.482549
Dates	0.3	0.592497	1.526054
Sugar/honey	1.3	6.188641	4.424254
Tea	1.3	0.636757	0.459118
Coffee	0.4	0.542689	1.217037

^a $\lambda = \sigma_w^2 / \sigma_b^2$

9.1.4. Discussion

In this section the level of agreement between the FFQ and the two 24 hour dietary recalls was presented for a subsample ($n = 98$) from the original cohort of participants ($n = 2631$). Dietary self-report instruments have measurement error, and several reasons have been proposed for this intrinsic limitation. Self-report dietary instruments rely on memory, therefore participants may find it difficult to recall their actual intakes, under or over reporting affects reported intakes because of social factors, and translation of frequencies and portion sizes of foods to actual intake may be imperfect (Freedman et al. 2011).

Comparing the FFQ with the 24 hour dietary recalls, similar values were observed for white and brown breads suggesting a consistency in estimating these food items. However, there was a significant difference for the remaining food items (eggs, milk, fruits, dates, sugar/honey, tea and coffee). One explanation to these differences is that it

is possible that portion size offered in the FFQ lead to over or under estimation of the actual portion consumed (Salvini et al. 1989, Willett and Hu 2007, Coulston and Boushey 2008). Another reason is that people tend to over report desirable foods or foods that are known to be healthy and under report undesirable foods (Salvini et al. 1989). For instance, participants over reported their intake of fruits, dates and milk. Although there was no significant difference between the FFQ and the 24 hour recalls, a similar trend was observed for white and brown breads. Participants reported higher intakes of brown breads and lower intakes of white breads in the FFQ.

The crude correlation coefficients of the FFQ used in this study ranged from 0.302 to 0.619, these correlations are comparable to other food based validation studies of dietary questionnaires (Salvini et al. 1989, Bogers et al. 2004, Kobayashi et al. 2011, Barbieri et al. 2014). The crude and energy adjusted correlations coefficients varied amongst foods; in particular, correlations were high for dates, tea and coffee. Researchers have found that it is easier for participants to report frequently eaten foods that are not affected by seasonal variation (Jain et al. 1980, Salvini et al. 1989) which may explain the observed variation.

Walter Willett found that adjustment for energy intake increases the crude correlation coefficient when variability of nutrient intake is related to energy intake (Willett 1998). However, in this study the correlation coefficient decreased after adjustment for energy intake. The decreased energy adjusted correlations have been reported in previous validation studies (Munger et al. 1992, Riley et al. 1995, Slater et al. 2003). Correlation coefficients decreased after energy adjustment because the variability of nutrient depended on measurement error, within- and between- person variance, and of overestimation and underestimation (Willett 1998). In calibration studies, measurement

error can be corrected by a minimum of two replicates of the reference tool (Carroll et al. 1997), as was conducted in this study. The energy-adjusted correlations were corrected by variance. The de-attenuated correlation coefficients (mean $r = 0.63$) in this study are comparable to the mean correlations in the study by Franceschi et al. (mean $r = 0.67$) (Franceschi et al. 1993) and slightly higher to that found in the study by Barbieri et al. (mean $r = 0.41$) (Barbieri et al. 2014).

Based on the average of two 24 hour recalls, the variance ratio of within- to between-person variance was greater than one for most foods. High variance ratio has been previously reported for nutrient and food intake (Beaton et al. 1979, Beaton et al. 1983, Feskanich et al. 1993, Slater et al. 2003). The lowest variance ratio was observed for dates and coffee which are staple dietary items in the Saudi diet (Alsaif et al. 2007). For dates and coffee, within person variance was lower than between person variance, which suggests that participants consumption was not affected by day-to day intake variation (Willett 1998). The highest variance ratio observed was for eggs (10.6). Willett suggested that errors in measuring actual intake would lead to a higher within person variance (Willett 1998). It is possible that participants may have found it difficult to report the actual amount of eggs consumed. For instance, if participants consumed a ready-made egg sandwich or omelette they would find it difficult to quantify the actual portion consumed. We expected to achieve a lower variance ratio for white bread intake, because they are commonly consumed in Saudi Arabia (Almana 2000). However, the omission of two main breads (Samooli, Tamees) may have led to the high variance ratio (Willett 1998). The two breads were not included because the FFQ question that assessed them was of poor structure (Chapter 6 - Dietary measurements preparation and cleaning).

Nevertheless, correction of the crude correlations between the FFQ and the two 24 hour dietary recalls for measurement error provided more accurate information regarding the validity of the questionnaire. Improvements in the correlation coefficients were observed for foods with an elevated variance ratio, such as egg intake.

Overall, this analysis documents that the FFQ showed reasonable agreement with the mean of the two 24 hour recalls, therefore, dietary data from this questionnaire can be reported. Nevertheless, the procedure of energy adjustment and within- to between-person variance was essential to obtain more accurate estimates of the correlation coefficient values. Furthermore, adjustment for energy intake and measurement error when reporting the diet-disease relationship, relying on FFQ, is important to increase the accuracy of associations.

Summary

In this section methods, results and discussion of the FFQ calibration study were presented for a sub-sample ($n = 98$) from the original cohort of participants ($n = 2631$). The level of agreement between the FFQ and the two 24 hour dietary recalls was presented. In the next section (Chapter 9 - section 2), the associations of selected foods and beverages with T2DM will be presented.

Section 2 Dietary factors and T2DM, the role of selected food and beverages and T2DM

Introduction

In this section, the associations between selected dietary variables (food items) and T2DM are presented for participants with newly diagnosed diabetes and with no diabetes ($n = 1867$) from the original BSR cohort ($n = 2631$), with analyses stratified by sex and diabetes status.

9.2.1. Methods

A) Nutritional tool – the FFQ

In brief, a semi quantitative FFQ was administered in the Biomarkers Research Program (2009). The questionnaire was developed by the nutritional department at King Saud University, Riyadh Saudi Arabia. The questionnaire assessed the amount and type of various foods on a daily, weekly and monthly basis. The FFQ was completed by physicians and trained research nurses. Further details of the dietary measures were previously described in Chapter 6 – The biomarkers screening in Riyadh (2009) survey methods: 6.10. Dietary measures.

B) Food items selection

The dietary dataset of 2631 participants included 135 dietary variables. Following careful screening of the questions structure and dietary data, 17 dietary variables were

suitable for analysis. Out of the 135 dietary variables 45 did not report the quantity measures (i.e. cups, grams), 3 questions combined different foods of different nutritional values under one question, 70 reported values that were difficult to interpret (i.e. reported the amount without the frequency, reported the frequency without the amount, the amount reported was not realistic). The 17 food items that were suitable for analysis were apple, pear, orange, banana, dates, egg, milk, sugar/honey, brown bread shami, white bread shami, regular brown bread, regular white bread, brown toast, white toast, shaboora, tea and coffee.

C) Sample selection

The original sample of this project was 2631 which consisted of participants with type 2 diabetes, impaired fasting glucose and with normal glycaemic status. Participants with newly diagnosed diabetes (unaware of their condition at the time of the 2009 survey) and with no diabetes were selected for this dietary analysis. A comparison was conducted between newly diagnosed and aware of their condition. The results showed significant differences in dietary variables (available in Appendix 12). The selection of newly diagnosed diabetes was to minimize reverse causation, which is common in cross-sectional studies. The flow diagram 9.2. shows the sample selection for these analyses.

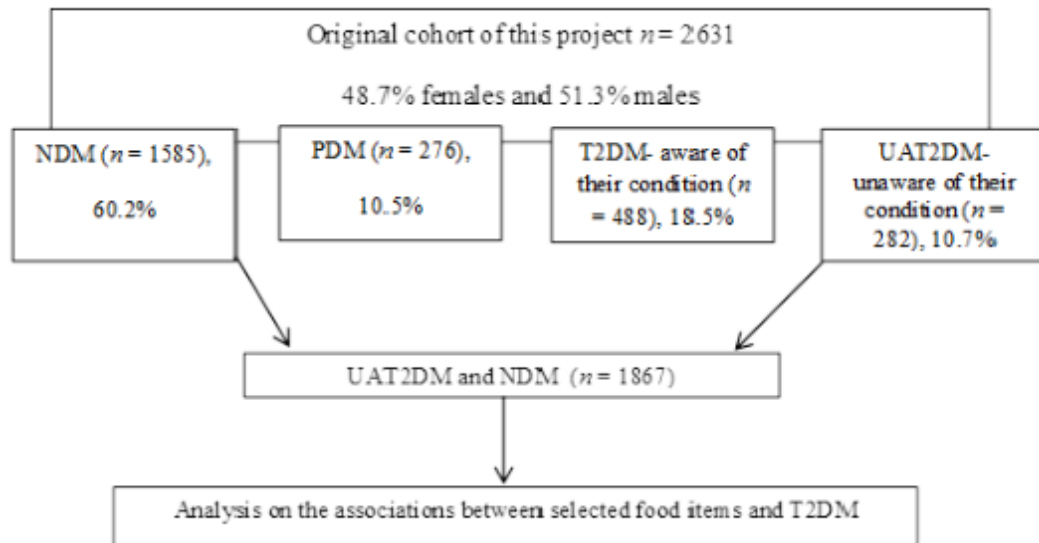


Figure 9.2. Sample selection for dietary analysis of section 2 – Chapter 9

9.2.2. Analysis

A) Nutritional analysis

Details on data preparation, cleaning and entry were previously mentioned in Chapter 6 – The biomarkers screening in Riyadh (2009) survey methods (6.15.). Dietary data (i.e. calories, grams) were exported from the Tinuviel nutritional software QBuilder V2.0. to SPSS Statistics V.21. for statistical analysis. As mentioned previously (in the first section of this chapter), the methods of Thompson et al. (Thompson et al. 2002) were followed to estimate servings/day. Briefly, the serving size of each food was obtained from the Food Dome dietary guidelines for Arab countries (Musaiger 2012). For example, if a respondent reported eating 90 grams of white Shami bread 4 times per week; this translated to 3 servings * 0.571 times per day, or 1.71 servings per day from white Shami bread. Each food group (i.e. white bread) included the sum of servings of the different white breads assessed by the questionnaire.

B) Statistical analysis

For descriptive analysis the ANOVA test was carried out for continuous variables and chi square test was carried out for categorical variables. The aim was to run a conservative model to minimise over adjustment, the selection of covariates was informed by the literature on the physiopathology and risk factor of T2DM (Chapter 3 – Literature review) and the descriptive characteristics of the overall sample (Chapter 7 – Descriptive characteristics of the 2631 participants of this project). A regression model was used to explore the associations between dietary variables and T2DM. The dependent variable was diabetes (NDM, UA-T2DM) and food items were the independent variables. For the overall sample, covariates included: age, sex, anthropometric measures (BMI, WC), socio-demographic variables (marital status, education level), family history of diabetes, lifestyle variables (physical activity, caloric intake from available dietary data), and history of GDM in females. Adjustment for measurement error (within-to between person variance) was carried out.

Sex-specific analyses were performed to assess the association between dietary variables and T2DM in males and females separately. Covariates included: age, anthropometric measures (BMI, WC), socio-demographic variables (marital status, education level), family history of diabetes, lifestyle variables (physical activity, caloric intake from available dietary data), history of gestational diabetes in females and measurement error (within-to between person variance). The descriptive analysis (presented below), for both the sex stratified and sex-diabetes stratified, showed no significant differences for family history of diabetes. Therefore, a sensitivity analysis was conducted with and without family history of diabetes (data not shown). The results

were consistent with and without the covariate (family history of diabetes), therefore the covariate was excluded from the model to avoid over adjustment.

Correction of the regression coefficient for measurement error was computed following Stram (Stram et al. 2000) and Willett methods (Willett 1998). The first step was to regress the “true” measure (food item from the mean of the two 24 hour dietary recalls from the calibration study – presented in the first section of this chapter) on the surrogate measure (food item from the FFQ) to obtain a regression coefficient (Υ). The second step was to correct the observed regression coefficient (β_o) describing the association between the food/beverage items from the surrogate measure (FFQ) and the dependent variable (diabetes).

The adjustment of observed estimates was as follows:

$$B_{\text{Adjusted}} = \beta_o / \Upsilon.$$

The adjustment of standard error (SE) was:

$$SE_{\text{Adjusted}} = \sqrt{(SE / \Upsilon)^2} = SE / \Upsilon.$$

The adjusted 95% CI was:

$$CI_{\text{Adjusted}} = \beta_{\text{Adjusted}} \pm (1.96 * SE_{\text{Adjusted}}).$$

The adjusted OR estimate was:

$$OR_{\text{Adjusted}} = \exp(\beta_{\text{Adjusted}}).$$

The adjusted 95% CI for the OR was:

$$CI_{\text{Adjusted}} = \exp(\beta_{\text{Adjusted}} \pm (1.96 * SE_{\text{Adjusted}}))$$

Significance (p value) was computed in R software using the following syntax:

- If estimate was negative: $p\text{-value} = 2 * (\text{pnorm}(\text{estimate}/\text{SE}))$
- If estimate was positive: $p\text{-value} = 2 * (1 - \text{pnorm}(\text{estimate}/\text{SE}))$

9.2.3. Results

A) Descriptive characteristics

Table 9.5. provides the characteristics of the overall sample for this study ($n = 1867$) which includes participants without diabetes and those unaware of their diabetes status at the time of the 2009 survey. All descriptive characteristics had similar trends to those observed in the overall sample of this project ($n = 2631$, available in Chapter 7 – Descriptive characteristics of the 2631 participants of this project). The mean age was 37.31 years, and males were significantly older than females. More than half of the sample was either overweight or obese (32.7% and 37.6% respectively) with a mean BMI of 28.57 kg/m². However, women had a significantly higher BMI than men (29.38 vs. 27.73 kg/m² respectively). The mean values of WC were 91.95 cm for the overall sample, however, males had a wider WC (95.00 cm) in comparison to females (89.06 cm) $p < 0.001$.

The majority of participants were married (67.0%) and almost half had a pre-college education (46.0%). The prevalence of hypertension was 15.7% and dyslipidaemia was 92.4%, chronic conditions were significantly more prevalent amongst males in comparison to females ($p < 0.001$). Over 80% of participants reported a family history of diabetes, and the majority reported a first-degree family history of diabetes (41.1%), but there was no significant difference for family history of diabetes between males and

females. Mean values for physiological and biochemical parameters for the overall sample were as follows: systolic blood pressure 117.54 mmHg, diastolic blood pressure 76.08 mmHg, FPG 5.58 mmol/L, and lipid profile (TC 4.99, TG 2.47, LDL-C 3.35, and HDL-C 0.88 mmol/L).

Sex stratified analysis showed a significant difference for the majority of dietary variables between males and females. The overall sample consumed more white breads (2.31servings/day) in comparison to brown breads (1.44 servings/day). However, males reported a significantly higher intake of brown bread (1.48 servings/day) in comparison to females (1.48 vs. 1.40 servings/day respectively, $p = 0.031$). Males, in comparison to females, consumed significantly more eggs (1.55 vs. 1.48 servings/day, $p < 0.001$), fruits (2.57 vs. 2.42 servings/day, $p = 0.008$), dates (4.15 vs. 3.39 servings/day, $p < 0.001$), tea (3.45 vs. 2.81 cups/day, $p < 0.001$), coffee (3.41 vs. 3.15 cups/day, $p = 0.013$), and sugar/honey (5.11 vs. 4.33 teaspoons/ day, $p < 0.001$). The majority of the sample reported the use of full fat cow's milk (71.7%) and Khalas dates consumption (57.2%), and these figures were the same amongst males and females.

Table 9.5.Descriptive* characteristics of the sample

Variable	Overall	Females	Males	<i>p</i>
<i>n</i>	1867	950	917	
Age (yrs)	37.31±14.44	35.52±12.67	39.17±15.87	<0.001
Sex				
Female	50.9% (950)			
Male	49.1% (917)			
Weight (kg)	75.25±17.45	71.82±16.73	78.80±17.47	<0.001
BMI (kg/m²)	28.57±6.32	29.38±6.71	27.73±5.77	<0.001
Underweight	4.4% (81)	4.7% (44)	4.1% (37)	<0.001
Normal weight	25.3% (463)	22.4% (209)	28.3% (254)	
Overweight	32.7% (598)	29.1% (271)	36.4% (327)	
Obese	37.6% (689)	43.8% (408)	31.3% (281)	

WC (cm)	91.95±15.67	89.06±15.52	95.00±15.25	<0.001
WHR	0.88±0.12	0.84±0.10	0.93±0.11	<0.001
SAD (cm)	23.37±8.68	23.28±9.64	23.47±7.65	0.677
Marital status				
Single	28.6% (524)	29.3% (274)	28.0% (250)	<0.001
Married	67.0% (1225)	62.4% (583)	71.8% (642)	
Divorced	1.7% (32)	3.3% (31)	0.1% (1)	
Widowed	2.6% (48)	5.0% (47)	0.1% (1)	
Education level				
Illiterate	23.1% (405)	32.7% (295)	12.9% (110)	<0.001
Pre-college	46.0% (806)	39.4% (355)	53.0% (451)	
College or Higher	30.9% (542)	27.9% (252)	34.1% (290)	
Free from HTN	15.7% (246)	87.9% (705)	80.6% (620)	<0.001
HTN	84.3% (1325)	12.1% (97)	19.4% (149)	
NDM	84.9% (1585)	86.5% (822)	83.2% (763)	0.026
UA-T2DM	15.1% (282)	13.5% (128)	16.8% (154)	
No family history	19.5% (269)	18.4% (133)	20.6% (136)	0.145
1 st degree family history	41.1% (568)	39.3% (284)	43.0% (284)	
2 nd degree family history	16.3% (226)	16.9% (122)	15.7% (104)	
1 st & 2 nd degree family history	23.1% (320)	25.3% (183)	20.7% (137)	
Free from lipid abnormalities				
abnormalities	7.6% (140)	10.9% (102)	4.2% (38)	<0.001
Lipid abnormalities	92.4% (1695)	89.1% (831)	95.8% (864)	
Systolic (mmHg)	117.54±13.44	115.33±13.12	119.85±13.39	<0.001
Diastolic (mmHg)	76.08±8.47	74.63±8.43	77.59±8.25	<0.001
FPG (mmol/L)	5.58±1.31	5.51±1.31	5.66±1.32	0.040
TC (mmol/L)	4.99±1.19	4.95±1.16	5.04±1.22	0.119
TG (mmol/L)	2.47±1.39	2.66±1.32	2.66±1.42	<0.001
LDL-C (mmol/L)	3.35±1.05	3.28±1.02	3.42±1.09	0.006
HDL-C (mmol/L)	0.88±0.34	1.00±0.34	0.74±0.29	<0.001
White breads (serving/day)	2.31±2.90	2.27±2.25	2.35±2.32	0.385
Brown breads (serving/day)	1.44±1.74	1.40±1.70	1.48±1.77	0.031
Egg (serving/day)	1.51±1.24	1.48±1.23	1.55±1.26	<0.001
Milk (serving/day)	2.62±1.12	2.62±1.14	2.64±1.11	0.787
Type of milk				
Cows full fat	71.7% (1240)	70.9% (621)	72.5% (619)	0.001
Cows low fat	13.4% (232)	14.0% (123)	12.8% (109)	
Cows skimmed fat	2.0% (35)	2.4% (21)	1.6% (14)	

Soya	0.3% (6)	0.2% (2)	0.5% (4)	
Goats	4.5% (77)	4.6% (40)	4.3% (37)	
Camels	2.6% (45)	1.1% (10)	4.1% (35)	
Non users	5.5% (95)	6.7% (59)	4.2% (36)	
Fruits (serving/day)	2.49±1.38	2.42±1.39	2.57±1.35	0.008
Dates (serving/day)	3.75±1.92	3.39±1.81	4.15±2.00	<0.001
Type of dates				
Sukari	30.6% (422)	27.3% (201)	34.3% (221)	0.001
Nboot Saif	5.9% (82)	7.7% (57)	3.9% (25)	
Sultana	3.0% (41)	2.6% (19)	3.4% (22)	
Khalas	57.2% (789)	59.6% (439)	54.3% (350)	
Other	3.3% (46)	2.7% (20)	4.0% (26)	
Tea (cups/day)	3.13±1.76	2.81±1.74	3.45±1.72	<0.001
Coffee (cups/day)	3.27±1.95	3.15±1.89	3.41±2.00	0.013
Sugar/Honey (teaspoon/day)	4.69±2.39	4.33±2.35	5.11±2.41	<0.001

* Percentage (n) or mean values ± SD

p value indicates the statistical difference between females and males.

BMI indicates body mass index; **Underweight** < 18.5 kg/m², **Normal weight** 18.5-24.99 kg/m², **Overweight** ≥ 25 kg/m², **Obese** ≥ 30 kg/m²; **WC** indicates waist circumference; **WHR** indicates waist to hip ratio (waist (cm)/hips (cm)); **SAD** indicates sagittal abdominal diameter in cm; **FPG** indicates fasting plasma glucose; **TC** indicates total cholesterol; **TG** indicates triglycerides; **HTN** indicates self-reported hypertension and/or use of HTN drugs or systolic ≥140 mmHg or diastolic ≥90 mmHg; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **UA-T2DM**: unaware of type 2 diabetes mellitus at the time of the 2009 survey (FPG ≥7.0 mmol/L; ≥126 mg/dL); **Family history of diabetes**: 1st degree includes father, mother, siblings or children. 2nd degree includes uncle, aunt, grandparents or grandchildren. **Lipid abnormalities** indicates self-reported dyslipidaemia and/or intake of lipid lowering drugs and/or lipid levels (TC ≥ 5.2, TG ≥ 1.7 mmol/L, LDL-C ≥ 2.6, HDL-C < 1.03).

Table 9.6. provides the descriptive characteristics of the overall sample stratified by sex and diabetes status. Traditional risk factors increased significantly amongst males and females with diabetes, such as age and anthropometric measures. However, females with diabetes were heavier (BMI 32.59 kg/m²) in comparison to males with diabetes (28.80 kg/m²), and had a higher prevalence of obesity (69.8% vs. 35.1% respectively). Education levels were significantly lower amongst diabetics, in both females and males, in comparison to non-diabetics (*p* < 0.05). The prevalence of chronic conditions (HTN and lipid abnormalities) was significantly higher amongst diabetics in comparison to non-diabetics. However, there was no significant difference in the prevalence of family history of diabetes. All biochemical parameters were significantly higher amongst males and females with diabetes except for HDL-C (*p* > 0.05).

Differences in the consumption of some food items between diabetes groups were observed in males. There was no significant difference in the consumption of white breads amongst diabetics and non-diabetics. However, males with diabetes consumed higher servings of brown breads in comparison to non-diabetics (1.63 vs. 1.45 respectively, $p = 0.027$). The majority of participants consumed full fat cow's milk; however, reports on the consumption of fat dense milk (i.e. goats, camels) were higher amongst males and females with diabetes in comparison to non-diabetics. Males with no diabetes consumed less fruits in comparison to diabetics ($p = 0.036$) but more dates ($p = 0.005$). Khalas dates intake were the most frequently type of date consumed by both diabetics and non-diabetics. Females with diabetes consumed more tea in comparison to non-diabetics. Although diabetics, both males and females, consumed more coffee and sugar/honey in comparison to non-diabetics, the difference was not significant.

Table 9.6. Descriptive* characteristics stratified by sex and diabetes status

Variable	Females			Males		
	NDM	UA-T2DM	<i>p</i>	NDM	UA-T2DM	<i>p</i>
n						
Age (yrs)	34.00±12.07	45.25±12.14	<0.001	37.67±15.47	46.53±15.80	<0.001
Weight (kg)	70.69±16.82	79.03±14.28	<0.001	78.27±17.47	81.50±17.29	0.040
BMI (kg/m²)	28.87±6.69	32.65±5.94	<0.001	27.52±5.78	28.80±5.64	0.014
Underweight	5.5% (44)	0.0% (0)	<0.001	4.8% (36)	0.7% (1)	0.032
Normal weight	24.2% (195)	11.2% (14)		29.3% (220)	23.0% (34)	
Overweight	30.6% (247)	19.2% (24)		35.4% (266)	41.2% (61)	
Obese	39.8% (321)	69.8% (87)		30.5% (229)	35.1% (52)	
WC (cm)	87.96±15.42	96.33±14.23	<0.001	94.29±15.30	98.62±14.50	0.003
WHR	0.83±0.11	0.88±0.08	<0.001	0.92±0.12	0.96±0.10	0.001
SAD (cm)	23.11±9.85	24.49±7.91	0.211	23.26±7.96	24.48±5.84	0.109
Marital status						
Single	32.4% (262)	9.4% (12)	<0.001	30.3% (226)	16.1% (24)	0.005
Married	60.3% (487)	75.6% (96)		69.4% (517)	83.9% (125)	
Divorced	3.3% (27)	3.1% (4)		0.1% (1)	0.0% (0)	

Widowed	4.0% (32)	11.8% (15)		0.1% (1)	0.0% (0)	
Education level						
Illiterate	28.9% (226)	57.0% (69)	<0.001	12.1% (86)	17.0% (24)	0.010
Pre-college	40.5% (316)	32.2% (39)		51.7% (367)	59.6% (84)	
College or Higher	30.6% (239)	10.7% (13)		36.2% (257)	23.4% (33)	
Free from HTN	90.0% (630)	73.5% (75)	<0.001	83.5% (536)	66.1% (84)	<0.001
HTN	10.0% (70)	26.5% (27)		16.5% (106)	33.9% (43)	
No family history	18.3% (115)	19.6% (18)	0.606	20.8% (116)	19.2% (20)	0.910
1 st degree family history	39.0% (246)	41.3% (38)		43.3% (241)	41.3% (43)	
2 nd degree family history	17.6% (111)	12.0% (11)		15.6% (87)	16.3% (17)	
1 st & 2 nd degree family history	25.1% (158)	27.2% (25)		20.3% (113)	23.1% (24)	
Free from dyslipidemia	12.3% (99)	2.3% (3)	<0.001	4.8% (36)	1.3% (2)	0.050
Dyslipidemia	87.7% (706)	97.7% (125)		95.2% (713)	98.7% (151)	
Systolic (mmHg)	114.04±12.1	124.21±16.1	<0.001	118.76±12.8	125.42±14.6	<0.001
Diastolic (mmHg)	73.94±8.20	79.36±8.52	<0.001	77.21±7.94	79.52±9.48	0.004
FPG (mmol/L)	5.04±1.12	9.63±1.34	<0.001	5.10±1.12	9.36±1.36	<0.001
TC (mmol/L)	4.87±1.14	4.87±1.17	<0.001	4.90±1.11	5.69±1.47	<0.001
TG (mmol/L)	2.21±1.29	2.93±1.38	<0.001	2.52±1.38	3.50±1.46	<0.001
LDL-C (mmol/L)	3.24±1.01	3.51±1.02	0.009	3.37±1.02	3.66±1.36	0.003
HDL-C (mmol/L)	1.01±0.33	0.95±0.35	0.053	0.75±0.29	0.70±0.30	0.073
White breads (serving/day)	2.27±2.25	2.26±2.31	0.928	2.33±2.30	2.47±2.42	0.424
Brown breads (serving/day)	1.40±1.71	1.41±1.65	0.904	1.45±1.75	1.63±1.86	0.027
Egg (serving/day)	1.47±1.22	1.51±1.25	0.284	1.54±1.25	1.61±1.27	0.092
Milk (serving/day)	2.62±1.15	2.62±1.04	0.960	2.64±1.12	2.61±1.06	0.766
Type of milk						
Cows full fat	71.1% (541)	69.6% (80)	0.147	73.6% (523)	67.1% (67.1)	<0.001
Cows low fat	13.9% (106)	14.8% (17)		13.1% (93)	11.2% (16)	
Cows skimmed fat	2.4% (18)	2.6% (3)		1.5% (11)	2.1% (3)	
Soya	0.3% (2)	0.0% (0)		0.6% (4)	0.0% (0)	
Goats	4.3% (33)	6.1% (7)		3.0% (21)	11.2% (16)	
Camels	0.8% (6)	3.5% (4)		3.5% (25)	7.0% (10)	
Non users	7.2% (55)	3.5% (4)		4.8% (34)	1.4% (2)	
Fruits (serving/day)	2.42±1.38	2.48±1.42	0.565	2.53±1.37	2.74±1.35	0.036
Dates (serving/day)	3.43±1.83	3.14±1.66	0.118	4.28±2.03	3.60±1.80	0.005
Type of dates						
Sukari	28.2% (182)	20.9% (19)	0.487	34.6% (188)	32.7% (33)	0.110
Nboot Saif	7.6% (49)	8.8% (8)		4.1% (22)	3.0% (3)	
Sultana	2.3% (15)	4.4% (4)		2.8% (15)	6.9% (7)	
Khalas	59.1% (381)	63.7% (58)		54.0% (293)	56.4% (57)	
Other	2.8% (18)	2.2% (2)		4.6% (25)	1.0% (1)	
Tea (serving/day)	2.76±1.74	3.11±1.71	0.051	3.45±1.76	3.46±1.56	0.970

Coffee (serving/day)	3.10±1.88	3.42±1.97	0.135	3.36±1.97	3.68±2.10	0.145
Sugar/Honey (teaspoon/day)	4.32±2.32	4.36±2.51	0.912	5.08±2.41	5.22±2.41	0.730

* Percentage (*n*) or mean values ± SD

UA-T2DM participants unaware of their diabetes at the time of the 2009 survey; *p* value indicates the statistical difference between non diabetics and T2DM; **BMI** indicates body mass index; **Underweight** < 18.5 kg/m², **Normal weight** 18.5-24.99 kg/m², **Overweight** ≥ 25 kg/m², **Obese** ≥ 30 kg/m²; **WC** indicates waist circumference; **WHR** indicates waist to hip ratio (waist (cm)/hips (cm)); **SAD** indicates sagittal abdominal diameter in cm; **FPG** indicates fasting plasma glucose; **TC** indicates total cholesterol; **TG** indicates triglycerides; **HTN** indicates self-reported hypertension and/or use of HTN drugs or systolic ≥140 mmHg or diastolic ≥90 mmHg; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **UA-T2DM**: unaware of type 2 diabetes mellitus (FPG ≥7.0 mmol/L; ≥126 mg/dL); **Family history of diabetes**: 1st degree includes father, mother, siblings or children. 2nd degree includes uncle, aunt, grandparents or grandchildren. **Dyslipidemia** indicates self-reported dyslipidaemia and/or intake of lipid lowering drugs and/or lipid levels (TC ≥ 5.2, TG ≥ 1.7 mmol/L, LDL-C ≥ 2.6, HDL-C <1.03).

B) Associations between selected food items and T2DM in the overall sample

Table 9.6. shows the associations between the selected food items and T2DM for the overall sample. Higher intakes of white breads (serving/day) had a borderline association with diabetes (OR 2.09, 95% CI 0.91-4.80, *p* = 0.081). Increased consumption of dates (serving/day) showed a significant inverse association with T2DM in the overall sample (OR 0.19, 95% CI 0.05-0.64, *p* = 0.007). The remaining food items (brown breads, egg, sugar/honey, fruits) showed no associations with diabetes in the overall sample.

Table 9.7. Association between food variables and T2DM in the overall sample

White breads (servings/day)				
Model	β	OR	CI	<i>p</i> for linearity
Model1	0.102	1.11	0.78-1.57	0.566
Model2	0.236	1.26	0.88-1.81	0.201
Model3	0.350	1.42	0.96-2.09	0.078
Model4	0.419	1.52	1.02-2.27	0.042
Model5	0.425	1.53	0.95-2.47	0.082
Model6	0.739	2.09	0.91-4.80	0.081
Brown breads (servings/day)				
Model	β	OR	CI	<i>p</i> for linearity
Model1	0.456	1.59	0.97-2.60	0.064
Model2	0.359	1.43	0.85-2.40	0.174
Model3	0.306	1.35	0.78-2.35	0.276
Model4	0.286	1.33	0.74-2.36	0.329

Model5	0.179	1.19	0.64-2.26	0.572
Model6	0.274	1.31	0.51-3.38	0.572
Eggs (serving/day)				
Model	β	OR	CI	<i>p</i> for linearity
Model1	0.261	1.31	0.97-1.73	0.077
Model2	0.372	1.45	1.07-1.95	0.015
Model3	0.356	1.43	1.03-1.97	0.032
Model4	0.324	1.38	0.99-1.92	0.054
Model5	0.190	1.21	0.85-1.70	0.276
Model6	0.442	1.55	0.71-3.42	0.272
Fruits (serving/day)				
Model	β	OR	CI	<i>p</i> for linearity
Model1	0.172	1.18	0.99-1.41	0.051
Model2	0.114	1.12	0.93-1.34	0.222
Model3	0.177	1.19	0.98-1.45	0.078
Model4	0.182	1.20	0.98-1.46	0.075
Model5	0.160	1.17	0.95-1.44	0.134
Model6	0.395	1.48	0.89-2.48	0.134
Dates (serving/day) no family				
Model	β	OR	CI	<i>p</i> for linearity
Model1	-0.645	0.52	0.34-0.82	0.005
Model2	-0.758	0.46	0.29-0.75	0.002
Model3	-0.813	0.44	0.27-0.74	0.002
Model4	-0.790	0.45	0.26-0.77	0.004
Model5	-0.746	0.47	0.27-0.82	0.008
Model6	-1.68	0.19	0.05-0.64	0.007
Sugar/honey (tsp/day)				
Model	β	OR	CI	<i>p</i> for linearity
Model1	0.089	1.09	0.78-1.52	0.602
Model2	0.068	1.07	0.75-1.51	0.702
Model3	0.091	1.09	0.75-1.59	0.633
Model4	0.046	1.05	0.71-1.55	0.819
Model5	0.072	1.07	0.68-1.68	0.753
Model6	0.395	1.48	0.13-15.90	0.744

Model summary: Model 1. Unadjusted; Model 2. Adjusted for sex and age; Model 3. Adjusted as previous plus anthropometric variables (BMI and WC); Model 4. Adjusted as previous plus socio-demographic variables (marital status and education level); Model 5. Adjusted as previous plus lifestyle variables (physical activity and caloric intake); Model 6. Adjusted as previous plus regression calibration (measurement error).

C) Associations between beverage intake and T2DM in the overall sample

Table 9.7. shows the associations between selected beverages and T2DM in the overall sample. Coffee consumption was inversely associated with T2DM in the unadjusted model but this association attenuated and was no longer significant after adjustment for covariates. Milk, tea and coffee intake (serving/day) showed inverse associations with T2DM. However, the associations did not reach statistical significance.

Table 9.8. Association between beverages variables and T2DM in the overall sample

Milk (cups/day)				
Model	β	OR	CI	<i>p</i> for linearity
Model1	-0.010	0.99	0.88-1.11	0.866
Model2	-0.020	0.98	0.86-1.10	0.738
Model3	-0.025	0.97	0.85-1.11	0.704
Model4	-0.031	0.96	0.84-1.11	0.656
Model5	-0.081	0.98	0.85-1.13	0.805
Model6	-0.304	0.49	0.43-1.26	0.267
Tea (cups/day)				
Model	β	OR	CI	<i>p</i> for linearity
Model1	0.063	1.07	0.99-1.14	0.093
Model2	0.003	1.00	0.92-1.08	0.937
Model3	0.017	1.01	0.93-1.11	0.684
Model4	0.012	1.01	0.92-1.10	0.793
Model5	-0.002	0.99	0.91-1.09	0.959
Model6	-0.01	0.99	0.76-1.28	0.940
Coffee (cups/day)				
Model	β	OR	CI	<i>p</i> for linearity
Model1	0.083	1.08	1.00-1.17	0.029
Model2	0.027	1.02	0.95-1.11	0.493
Model3	0.011	1.01	0.92-1.10	0.807
Model4	-0.005	0.99	0.90-1.09	0.919
Model5	-0.015	0.98	0.89-1.08	0.756
Model6	-0.027	0.97	0.82-1.16	0.758

Model summary: Model 1. Unadjusted; Model 2. Adjusted for sex and age; Model 3. Adjusted as previous plus anthropometric variables (BMI and WC); Model 4. Adjusted as previous plus socio-demographic variables (marital status and education level); Model 5. Adjusted as previous plus lifestyle variables (physical activity and caloric intake); Model 6. Adjusted as previous plus

D) Sex stratified associations between selected food items and T2DM

Table 9.8. shows the associations between food intake and T2DM in females and males separately. White breads intake (serving/day) showed a positive association in both females and males but this association did not reach statistical significance. There was no association between brown breads intake (serving/day) and T2DM in both females and males. Similarly, eggs, fruits and sugar/honey were not associated with T2DM in both sexes. Nevertheless, dates intake (serving/day) showed an inverse association with T2DM in both females and males. In males, the association between dates consumption and T2DM reached statistical significance in the fully adjusted model (OR 0.16, 95% CI 0.04-0.65, $p = 0.01$) whilst this association attenuated in females.

E) Sex stratified associations between beverage intake and T2DM

Table 9.9. shows the associations between beverage intake and T2DM in females and males separately. Milk intake was inversely associated with T2DM in both sexes, however, this association did not reach statistical significance. Tea and coffee intake did not show any associations with T2DM in both females and males.

Table 9.9. Sex stratified associations between food intake and T2DM

Variable		Females				Males			
White breads (serving/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>	
Model1	-0.024	0.93	0.57-1.65	0.928	0.191	1.21	0.75-1.93	0.424	
Model2	0.149	1.16	0.67-2.00	0.595	0.307	1.36	0.84-2.20	0.211	
Model3	0.301	1.35	0.74-2.45	0.325	0.396	1.48	0.88-2.48	0.131	
Model4	0.377	1.45	0.79-2.67	0.225	0.451	1.56	0.91-2.69	0.103	
Model5	0.403	1.49	0.72-3.09	0.276	0.442	1.55	0.82-2.95	0.176	
Model6	0.510	1.66	0.76-3.66	0.205	-	-	-	-	
Model7	0.565	1.75	0.74-4.20	0.204	0.820	2.27	0.52-5.61	0.176	
Brown breads (serving/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>	
Model1	0.049	1.05	0.47-2.33	0.904	0.712	2.03	1.07-3.85	0.028	
Model2	-0.117	0.88	0.38-2.07	0.785	0.677	1.96	1.01-3.80	0.044	
Model3	-0.093	0.91	0.37-2.23	0.839	0.067	1.93	0.95-3.92	0.067	
Model4	-0.103	0.902	0.35-2.30	0.830	0.611	1.84	0.88-3.84	0.104	
Model5	-0.140	0.87	0.31-2.37	0.870	0.436	1.54	0.69-3.42	0.283	
Model6	-0.292	0.75	0.25-2.26	0.606	-	-	-	-	
Model7	-0.241	0.79	0.31-1.96	0.606	0.699	2.01	0.56-7.19	0.282	
Eggs (serving/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>	
Model1	0.345	1.41	0.78-2.54	0.250	0.213	1.23	0.88-1.72	0.210	

Model2	0.427	1.53	0.82-2.86	0.180	0.322	1.38	0.98-1.93	0.063
Model3	0.422	1.52	0.79-2.93	0.207	0.322	1.38	0.94-2.00	0.092
Model4	0.436	1.54	0.78-3.03	0.205	0.267	1.31	0.89-1.90	0.163
Model5	0.215	1.24	0.59-2.60	0.571	0.164	1.17	0.79-1.73	0.409
Model6	0.172	1.18	0.53-2.67	0.677	-	-	-	-
Model7	0.199	1.22	0.47-3.12	0.678	0.392	1.47	0.58-3.73	0.407
Fruits (serving/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>
Model1	0.093	1.09	0.83-1.44	0.506	0.209	1.23	0.98-1.55	0.074
Model2	0.033	1.03	0.78-1.37	0.818	0.172	1.18	0.93-1.50	0.157
Model3	0.120	1.12	0.83-1.52	0.440	0.218	1.24	0.95-1.61	0.106
Model4	0.155	1.16	0.85-1.59	0.326	0.200	1.21	0.93-1.59	0.144
Model5	0.094	1.09	0.78-1.53	0.576	0.199	1.22	0.92-1.60	0.155
Model6	0.133	1.14	0.79-1.64	0.477	-	-	-	-
Model7	0.135	1.36	0.78-1.66	0.477	0.616	1.85	0.50-4.32	0.154
Dates (serving/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>
Model1	-0.566	0.57	0.28-1.12	0.118	-0.831	0.44	0.24-0.78	0.005
Model2	-0.390	0.68	0.32-1.43	0.309	-0.928	0.39	0.22-0.72	0.003
Model3	-0.532	0.59	0.24-1.33	0.206	-0.961	0.38	0.18-0.74	0.004
Model4	-0.446	0.64	0.27-1.48	0.298	-1.023	0.36	0.18-0.72	0.004
Model5	-0.481	0.62	0.25-1.49	0.286	-0.938	0.39	0.19-0.80	0.010
Model6	-0.711	0.49	0.19-1.29	0.491	-	-	-	-
Model7	-2.86	0.11	0.001-2.77	0.148	-1.82	0.16	0.04-0.65	0.010
Sugar/honey (tsp/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>
Model1	0.028	1.03	0.62-1.70	0.911	0.080	1.08	0.68-1.70	0.730

Model2	-0.154	0.86	0.50-1.45	0.570	0.160	1.73	0.73-1.86	0.500
Model3	-0.041	0.96	0.53-1.71	0.890	0.140	1.15	0.69-1.90	0.584
Model4	-0.055	0.94	0.52-1.72	0.856	0.073	1.07	0.63-1.82	0.785
Model5	0.077	1.08	0.53-2.17	0.830	0.010	1.01	0.55-1.82	0.974
Model6	-0.026	0.97	0.43-2.18	0.951	-	-	-	-
Model7	-0.069	0.93	0.11-8.06	0.950	0.058	1.05	0.03-32.72	0.973

Model summary: Model 1. Unadjusted; Model 2. Adjusted for age; Model 3. Adjusted as previous plus anthropometric variables (BMI and WC); Model 4. Adjusted as previous plus socio-demographic variables (marital status and education level); Model 5. Adjusted as previous plus lifestyle variables (physical activity and caloric intake); Model 6. Adjusted as previous plus history of GDM in females; Model 7. Adjusted as previous plus regression calibration (measurement error).

Table 9.10. Sex stratified associations between beverage intake and T2DM

Variable	Females				Males			
Milk (cups/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>
Model1	0.004	1.00	0.85-1.18	0.960	-0.024	0.97	0.83-1.14	0.765
Model2	-0.005	0.98	0.83-1.17	0.863	-0.030	0.97	0.82-1.14	0.718
Model3	-0.012	0.98	0.81-1.19	0.988	-0.042	0.95	0.80-1.14	0.643
Model4	-0.19	0.98	0.80-1.19	0.850	-0.048	0.95	0.78-1.15	0.627
Model5	-0.033	0.96	0.78-1.19	0.759	-0.007	0.99	0.81-1.12	0.943
Model6	0.045	1.04	0.83-1.31	0.692	-	-	-	-
Model7	0.071	1.07	0.75-1.55	0.696	-0.031	0.96	0.40-2.33	0.944
Tea (cups/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>
Model1	0.106	1.11	0.99-1.23	0.052	0.002	1.00	0.90-1.11	0.970
Model2	0.037	1.03	0.92-1.16	0.529	-0.037	0.96	0.86-1.07	0.500
Model3	0.019	1.02	0.90-1.15	0.760	0.008	1.00	0.89-1.13	0.898
Model4	0.015	1.01	0.89-1.15	0.817	0.004	1.00	0.88-1.13	0.950
Model5	-0.005	0.99	0.87-1.13	0.948	-0.010	0.99	0.87-1.12	0.875
Model6	-0.011	0.98	0.85-1.14	0.885	-	-	-	-
Model7	-0.289	0.74	0.001-2.64	0.883	-0.03	0.93	0.69-1.35	0.859
Coffee (cups/day)	β	OR	CI	<i>p</i>	β	OR	CI	<i>p</i>
Model1	0.083	1.08	0.97-1.21	0.136	0.077	1.08	0.97-1.19	0.146
Model2	0.012	1.01	0.90-1.13	0.836	0.036	1.04	0.93-1.15	0.512
Model3	-0.022	0.97	0.86-1.10	0.728	0.027	1.03	0.91-1.15	0.650

Model4	-0.019	0.98	0.86-1.11	0.981	0.005	1.00	0.88-1.14	0.944
Model5	-0.024	0.97	0.85-1.11	0.729	-0.018	0.98	0.85-1.12	0.790
Model6	-0.034	0.96	0.83-1.19	0.646	-	-	-	-
Model7	-0.057	0.94	0.49-1.21	0.653	-0.031	0.96	0.76-1.22	0.794

Model summary: Model 1. Unadjusted; Model 2. Adjusted for age; Model 3. Adjusted as previous plus anthropometric variables (BMI and WC); Model 4. Adjusted as previous plus socio-demographic variables (marital status and education level); Model 5. Adjusted as previous plus lifestyle variables (physical activity and caloric intake); Model 6. Adjusted as previous plus history of GDM in females; Model 7. Adjusted as previous plus regression calibration (measurement error).

9.2.4. Discussion

In this section, associations between selected food and beverage items and T2DM were presented for a subsample ($n = 1867$) from the original cohort of participants in this project ($n = 2631$). The sample included participants who were unaware of their diabetes at the time of the survey (2009) and participants with no diabetes. The results showed that participants who were unaware of their diabetes reported a higher consumption of white breads in comparison to non-diabetics. White bread consumption showed a positive association with T2DM, however, the findings did not reach a formal level of statistical significance. The systematic review of this project highlighted the lack of nutritional evidence in the Gulf region, therefore it is difficult to compare observations of this study to local studies originating from Saudi Arabia or neighbouring countries in the Gulf region.

In line with the findings of this study, Esmailzadeh et al. found no association between refined grain consumptions (including white breads) and T2DM in 827 Iranian adults (Esmailzadeh et al. 2005). Similarly, the Nurses' Health Study in the US found no significant associations between refined grain intakes and risk of diabetes in 75 521 adult females (Liu et al. 2000). However, Hu et al. argues that the type of carbohydrates, such as white breads, plays a role in the risk of diabetes (Hu et al. 2001). The questionnaire in this study did not include two commonly consumed white breads (Samooli and Tamees) in Saudi Arabia (Almana 2000) and this may have attenuated the observed associations.

Similar to white breads intake, reports on egg consumption were higher amongst females and males with diabetes in comparison to non-diabetics. A large prospective epidemiological study, which used data from both the Physicians' Health Study and the Women's Health Study, examined the association between egg consumption and the risk of T2DM in 56,998 adults. The findings showed that daily egg intake was associated with a higher risk of T2DM (Djoussé et al. 2009). In this study, the unadjusted model showed a borderline association between eggs and T2DM in the overall sample. However, this association attenuated after adjustment for covariates. The structure of the question may have affected participants reports as egg intake was assessed by reporting the number of eggs consumed per week. Participants may have found it difficult to average the number of eggs consumed per week or quantify the amount consumed in different forms (i.e. eggs in the form of omelettes, eggs in sandwiches). Nevertheless, correction for measurement error was considered in this analysis.

Protective foods against diabetes, such as whole grains, fruit and vegetables, have been identified by Middle Eastern (Esmailzadeh et al. 2005, Esmailzadeh and Azadbakht 2008, Al Ali et al. 2011, Naja et al. 2012) and international studies (Fung et al. 2002, Montonen et al. 2003, de Munter et al. 2007). The prospective longitudinal Health Professionals cohort study found that the consumption of whole fruits was favourably associated with diabetes (Muraki et al. 2013). Similarly, the European Prospective Investigation of Cancer–Norfolk cohort study reported an inverse association between fruits intake and the risk of diabetes in 21831 adults (Harding et al. 2008). The evidence for the association

between fruits intake and T2DM remains controversial. Two meta-analyses of cohort studies showed no significant association between the consumption of fruits and risk of diabetes (Hamer et al. 2007, Carter et al. 2010). In this study, males who were unaware of their diabetes consumed significantly more servings of brown breads and fruits in comparison to non-diabetics. Similarly, diabetic females consumed more servings of fruits in comparison to non-diabetics but the increase was not significant. It is possible that participants with diabetes, in comparison to non-diabetics, may have had a higher consumption of foods in general. The findings showed no association between brown breads and fruits intakes and T2DM. Although whole grain consumption was found to be protective against diabetes in Middle Eastern populations (Esmailzadeh et al. 2005, Naja et al. 2012), comparing the findings of this study is problematic because of the heterogeneity of included foods. Omission of other types of brown breads and fruits available in the Saudi diet from the questionnaire may have affected participants' reports and the observed associations.

Reports on milk consumption were similar across groups in both females and males, and full fat cow's milk was reported by the majority of participants. Milk intake showed an inverse trend with diabetes, however, the association was not statistically significant. The inverse association between dairy intake and diabetes has been previously reported in Middle Eastern (Naja et al. 2012) and International settings (Choi et al. 2005, Liu et al. 2006). Similar to dairy consumption, the evidence suggests that tea and coffee consumption is associated with a lower risk of diabetes (Salazar-Martinez et al. 2004, Tuomilehto et al. 2004, Huxley et al. 2009). In this study, reports on tea consumption were lower

amongst females with diabetes in comparison to non-diabetics. Although an inverse trend was observed between tea and coffee intake and T2DM, no significant associations were observed.

Interestingly, dates consumption was higher amongst non-diabetics in comparison to diabetics. Specifically, males with no diabetes reported significantly higher intakes of dates in comparison to diabetics. Reports on higher consumption of dates (servings/day) showed a significantly inverse association with diabetes in the overall sample. This association remained statistically significant after adjustment for covariates. The sex-stratified analysis showed an inverse association between dates consumption and diabetes in both sexes. However, this association remained significant in males but not in females, likely as result of limited statistical power in subgroup analyses. Khalas was reported as the type of dates consumed by the majority of participants in this study. The glycaemic index of Khalas dates has been tested in 19 Saudi participants and was 57.7 (Ahmed et al. 1991) suggesting that dates did not have a high glycaemic index (Jenkins et al. 1981).

Miller et al. conducted a study in the United Arab of Emirates which examined the glycaemic index of locally grown dates in healthy adults. (Miller et al. 2002). The results showed that dates had a low glycaemic index, ranged from 35.5-47.2, which was lower than apples, oranges and bananas (Miller et al. 2002, Miller et al. 2003). Alkaabi et al. reported similar findings in participants with and without T2DM. The glycaemic index of five different dates, including Khalas has been tested in 13 adults with no diabetes and 10 adults with diabetes. The findings

showed no significant differences in the glycaemic response between diabetics and non-diabetics. The mean glycaemic index ranged from 43.8-53.0 in adults with diabetes suggesting that dates have a low glycaemic index (Alkaabi et al. 2011). It is therefore biologically plausible that dates may have a favourable effect on T2DM risk.

Summary

In this section, the methods, results and discussion of the associations of selected foods and beverages with T2DM were presented. The associations were presented for a subsample ($n = 1867$) of the original cohort ($n = 2631$). The subsample included participants who were unaware of their diabetes at the time of the 2009 survey and non-diabetics. In the next chapter (Chapter 10), the associations between dietary biomarkers (vitamin D and selenium) will be presented for a random sub-sample of the original cohort.

10 Dietary factors and T2DM: the role of dietary biomarkers

Introduction

In this chapter the associations of selected nutritional biomarkers (micronutrient status) and T2DM are presented for a random subsample ($n = 567$) of the original BSR cohort ($n = 2631$), with analyses stratified by sex. The micronutrients examined in this project are serum vitamin D (25 (OH) D) and serum selenium (Se).

10.1. Methods

A) Biomarkers selection

The selection of these two specific biomarkers was driven by the large body of evidence suggesting their potential role in diabetes etiology and prevention (Stranges et al. 2007, Laclaustra et al. 2009, Misu et al. 2010, Rees et al. 2013) and the lack of studies in Saudi populations as identified by the literature review of this project (Chapter 3). Other important biomarkers of nutritional status could have been chosen, but limited resources did not allow for this. The research centre in Saudi Arabia stored frozen serum samples of the original Biomarkers Screening survey cohort ($n = 2631$). Due to the availability of frozen serum only,

fasting insulin was the most appropriate surrogate marker for diabetes (Haffner et al. 1990) to further explore the associations between diabetes markers (FPG, fasting insulin) and dietary biomarkers. However, these associations were for descriptive reasons only as the main outcome of this project was the prevalence of T2DM.

B) Sample size calculation

Due to limited resources we could not analyse more than 600 samples. However, sample size calculations were conducted to ensure adequate power for the analyses. A specialist statistician (Dr. Shaun Sabico) was consulted for sample size calculations for this project. Sample size calculation was done using G*Power version 3.0.10. The calculation was based on tertiles of observed serum 25(OH)D concentrations between males and females across diabetes groups, with the lowest category as the reference. With an actual mean 25(OH)D 10.29 ± 1.29 for females and 17.89 ± 1.48 for males (refer to table 9.3), a sample size of $n = 34$ per group (102 males and 102 females) will have an observed effect size of 5.44 and a critical t of 2.03 given $\alpha = 0.05$ and 80% power. Based on our actual sample size which is 87 per group in males and 97 per group in females, the actual observed power is 99.6% and 99.8%, respectively, given $\alpha = 0.05$.

C) Sample selection

A random computer sample ($n = 600$) was generated from the original BSR cohort ($n = 2631$) using SPSS Statistics V.21. The sample was stratified by sex

and glycaemic status. Sex stratification was set *a priori* because of the biological and social differences between females and males (Bird and Rieker 1999), as well as due to well-established differences in diabetes etiology and natural history between the two sexes (Donahue et al. 2007, Donahue et al. 2011). The sample included three groups, non-diabetics ($n = 200$), unaware pre-diabetics ($n = 200$), and unaware T2DM ($n = 200$) with an equal distribution of sex for each group. Unaware indicates that participants were not aware of their condition at the time of the original survey in 2009, i.e. they were not previously diagnosed by a physician nor reported any diabetes or diabetes therapy.

The selection of participants with a new diagnosis of either pre-diabetes or type 2 diabetes should also minimize the potential for reverse causation, which is a well-known intrinsic limitation of cross-sectional studies. The serial number of the sample ($n = 600$) was sent to the biomarkers research centre in Saudi Arabia for laboratory analysis at an agreed cost. Due to the unavailability of some frozen serum samples we were left with 567 participants with available stored frozen serum samples.

D) Biochemical analysis

Laboratory technicians working for the biomarkers research centre in Saudi Arabia analysed the frozen serum samples. Members of the research centre entered the results, and a soft copy (Excel sheet) was emailed to the primary investigator. Serum 25 (OH) D was measured by enzyme linked immunosorbent assays (ELISA) in accordance to the instructions provided in the IDS catalogue

(IDS Ltd, Boldon Colliery, Tyne & Wear, UK). The inter- and intra-assay coefficients of variation (CV) for 25 (OH) D ELISA were 5.3% and 4.6%, respectively. Determination of serum insulin was carried out using customized multiplex assay kits that utilize the Luminex® xMAP® Technology platform (Luminexcorp, Austin, TX, USA). The intra-assay coefficient of variation was 1.4–7.9% and inter-assay coefficient of variation of < 21%. Minimum detectable concentration was 50.9 pg mL⁻¹.

Serum Se level was determined by Shimadzu graphite furnace atomic absorption spectrometry, Shimadzu, Model: AA- 7000 Series equipped with auto sampler. Pyrolytically coated tubes were used as atomizers. The conditions for Se were: A Shimadzu selenium hollow cathode lamp with wavelength of 196.0 nm, lamp current: 290 mA, slit width: 2.0 nm, matrix modifier was Paladium modifier. The detection limit of the method was less than 5 ug/L, precision (<11%) and inaccuracy (<1%). Samples were diluted in proportion 1:10 with a special reducing reagent containing Ascorbic acid, Triton X-100 and Antifoam B Emulsion in deionized water to improve the sample viscosity and reproducibility of the results. Stock standard solutions for selenium were prepared from the commercial Se standard (1000 mg/L) Solution Acros Organics (US). The working standard solutions were prepared weekly by appropriate dilution and kept refrigerated at 4 °C. Argon was applied as protective gas and 10 µL samples were injected into the graphite furnace (GF). All samples were analysed in duplicate. Human reference serum (Seronorm™Trace Elements in Serum) from Sero AS (Billingstad, Norway) was used to check the entire proposed analytical method reliability. This reference material was supplied in lyophilized form and

reconstituted by dissolving the vial total content using high purity de-ionized water. The over-all coefficient of variation for the selenium method used has been 3 - 4% over the entire analytical range. The results for the reference sample agreed with the certified acceptable range of selenium concentration.

10.2. Statistical analysis

Statistical analysis was conducted using the statistical package of social sciences SPSS Statistics V.21. Biomarker levels were explored in prior analysis, and histograms were generated to explore the distribution of variables. Serum 25 (OH) D and fasting insulin were logarithmically transformed to normalize the distribution, whilst serum Se was normally distributed and did not require any transformation. Continuous variables were described using means and standard deviations, and categorical variables were described as frequencies in percentages. Independent sample t-tests (for continuous variables) and chi-square tests (for categorical variables) were conducted to compare the difference in characteristics between the sub-sample and the original cohort. Sex-stratified tertiles of serum biomarkers (25 (OH) D and Se) were generated for multivariate analysis. There are no cultural specific cut-off levels of the selected biomarkers that may be associated with diabetes in the Saudi Arabia, therefore, the use of tertiles were set *a priori* to observe the trend in variables across groups.

Multivariate analysis was conducted using ANOVA for continuous variables, and the chi-square test for categorical variables. Correlations between serum biomarkers and the sub-sample characteristics were explored using the bivariate

Pearson correlation test for the overall sample and sex-stratified correlations. The significance of interaction between serum biomarkers and covariates (age, BMI) was tested using a logistic regression model for the overall sample and sex-stratified interaction. Age and sex adjusted univariate analysis was conducted to observe the difference in biomarker levels across diabetes groups, which was carried out for the overall sample, and in females and males separately (Bland 2000).

10.3. Results

A) Comparison between the sub-sample and the original cohort

Table 10.1. provides a general description of the random sub-sample ($n = 567$) which was selected for the biomarkers analysis in comparison to the original cohort ($n = 2631$) of this project. There were no significant differences between the sub-sample and the original cohort for most of the variables, such as age, anthropometrics measures, hypertension, and LDL-C.

Diabetes profile differed between the two cohorts; mean FPG levels were higher in the sub-sample (7.14 mmol/L) in comparison to the original cohort (6.82 mmol/L, $p = 0.034$), and the prevalence of glucose abnormalities (PDM and T2DM) was higher in the sub-sample (32.6%, 33.9% respectively) in comparison to the original cohort (4.4%, 28% respectively). However, this was a result of the selection criteria (mentioned above “methods of sample selection”). There was

no significant difference in family history of diabetes between groups. Lipid profile was higher ($p \leq 0.001$) in the sub-sample in comparison to original cohort, except for LDL-cholesterol. However, the overall prevalence of lipid abnormalities was not different between the two groups.

Table 10.1. Comparison* of characteristics between the sub-sample and the original cohort

Variable	Biomarkers sample	Original cohort	<i>p</i>
<i>n</i>	567	2631	
Age (yrs)	40.72±15.63	40.80±15.47	0.912
Sex (%)			
Female	52.7%	48.7%	0.078
Male	47.3%	51.3%	
Weight (kg)	76.81±17.32	76.63±17.32	0.826
BMI (kg/m ²)	29.33±6.39	29.16±6.36	0.558
Underweight	3.4% (19)	3.5% (91)	0.817
Normal weight	21.3% (118)	22.0% (568)	
Overweight	31.8% (176)	33.3% (858)	
Obese	43.4% (240)	41.2% (1062)	
WC (cm)	94.17±15.70	94.11±15.83	0.944
Hips (cm)	105.31±15.73	105.14±15.27	0.829
WHR	0.90±0.12	0.90±0.12	0.725
SAD (cm)	24.10±7.19	23.90±8.19	0.646
Systolic (mmHg)	120.93±13.87	120.26±14.41	0.354
Diastolic (mmHg)	77.86±8.19	77.41±8.62	0.299
FPG (mmol/L)	6.73±1.37	6.32±1.45	<0.001
TC (mmol/L)	5.24±1.26	5.08±1.21	0.006
TG (mmol/L)	2.76±1.42	2.58±1.40	<0.001
LDL-C (mmol/L)	3.40±1.10	3.40±1.05	0.963
HDL-C (mmol/L)	0.91±0.35	0.86±0.34	0.002
Free from HTN	76.9% (372)	24.4% (553)	0.556
HTN	23.1% (112)	75.6% (1713)	
NDM	33.5% (190)	74.4% (1585)	<0.001
UA-PDM	32.6% (185)	12.3% (262)	
UA-T2DM	33.9% (192)	13.9% (282)	
Family history of			

diabetes			
No family history	20.9% (86)	17.5% (345)	0.138
1 st degree family history	41.0% (169)	44.9% (884)	
2 nd degree family history	16.7% (69)	14.1% (278)	
1 st & 2 nd degree family history	21.4% (88)	23.4% (461)	
No lipid abnormalities	5.0% (28)	6.1% (157)	0.183
Lipid abnormalities	95.0% (537)	93.9% (2437)	

*Percentage (*n*) or mean values \pm SD; *p* value indicates the statistical difference between the biomarkers sample and original cohort; **BMI** indicates body mass index; **Underweight** ≤ 18.5 kg/m², **Normal weight** 18.5-24.99 kg/m², **Overweight** 25-29.99 kg/m², **Obese** ≥ 30 kg/m²; **WC** indicates waist circumference; **WHR** indicates waist to hip ratio (waist (cm)/hips (cm)); **SAD** indicates sagittal abdominal diameter in cm; **FPG** indicates fasting plasma glucose; **TG** indicates triglycerides; **HTN** indicates self-reported hypertension and/or use of HTN drugs or systolic ≥ 140 mmHg or diastolic ≥ 90 mmHg; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **UA-PDM**: unaware of pre-diabetes (FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **UA-T2DM**: unaware of type 2 diabetes mellitus (FPG ≥ 7.0 mmol/L; ≥ 126 mg/dL); **Family history of diabetes**: 1st degree includes father, mother, siblings or children. 2nd degree includes uncle, aunt, grandparents or grandchildren. **Lipid abnormalities** indicate self-reported dyslipidaemia and/or intake of lipid lowering drugs and/or lipid levels (TC ≥ 5.2 mmol/L and/or TG ≥ 1.7 mmol/L and/or LDL-C ≥ 2.6 mmol/L and/or HDL-C < 1.03).

B) Descriptive characteristics of the sub-sample

Table 10.2. provides a general description of the sub-sample (*n* = 567) which was randomly selected for biomarkers analysis. Similar to the baseline total sample (*n* = 2631), females had a significantly higher BMI in comparison to males, whilst WC and SAD were higher in males (96.21, 24.86 cm respectively) in comparison to females (92.35, 23.39 cm respectively). Females had significantly lower levels of 25 (OH) D (22.59 nmol/L) in comparison to males (33.35 nmol/L), whilst there was no significant sex-specific difference for selenium levels (*p* = 0.999). Males had significantly higher levels of fasting insulin (19.54 IU/ml) in comparison to females (15.92 IU/ml). There was no significant difference in the prevalence of lipid abnormalities between sexes, however, males had higher TG (3.02 mmol/L vs. 2.54 mmol/L, *p* < 0.001) and lower HDL-C levels (0.76 mmol/L vs. 1.03 mmol/L, *p* < 0.001). Vitamin consumption was relatively low in the overall sample at 7.5%, however, the

prevalence of intake was higher in females (11%) in comparison to males (3.4%).

Table 10.2. Descriptive* characteristics of the sub-sample

Variable	Overall	Females	Males	<i>p</i>
<i>n</i>	567	299	268	
Age (yrs)	40.72±15.63	40.94±14.44	40.46±16.88	0.715
Sex (%)				
Females	52.7% (299)			
Males	47.3% (268)			
BMI (kg/m²)	29.33±6.39	30.49±6.62	28.02±5.87	<0.001
Underweight	3.4% (19)	3.4% (10)	3.5% (9)	<0.001
Normal weight	21.3% (118)	17.3% (51)	25.9% (67)	
Overweight	31.8% (176)	25.2% (74)	39.4% (102)	
Obese	43.4% (240)	54.1% (159)	31.3% (81)	
WC (cm)	94.17±15.70	92.35±15.80	96.21±15.37	0.005
Hips (cm)	105.31±15.73	107.46±15.05	102.91±16.16	0.001
WHR	0.90±0.12	0.85±0.09	0.94±0.13	<0.001
SAD (cm)	24.10±7.19	23.39±6.11	24.86±8.16	0.032
Systolic (mmHg)	120.93±13.87	119.93±14.09	122.11±13.55	0.087
Diastolic (mmHg)	77.86±8.19	77.31±7.86	78.51±8.53	0.110
FPG (mmol/L)	6.73±1.37	6.71±1.38	6.75±1.37	0.839
Fasting insulin (IU/ml)	17.55±2.69	15.92±2.53	19.54±2.84	0.015
TC (mmol/L)	5.24±1.26	5.25±1.09	5.23±1.44	0.852
TG (mmol/L)	2.76±1.42	2.54±1.34	3.02±1.47	<0.001
LDL-C (mmol/L)	3.40±1.10	3.42±0.92	3.37±1.28	0.577
HDL-C (mmol/L)	0.91±0.35	1.03±0.34	0.76±0.29	<0.001
25 (OH) D (nmol/l)	27.16±1.96	22.59±2.02	33.35±1.78	<0.001
Se (ng/ml)	104.35±34.52	104.59±34.11	104.59±35.08	0.999
Free from HTN	76.9% (372)	78.7% (207)	74.7% (165)	0.173
HTN	23.1% (112)	21.3% (56)	25.3% (56)	
NDM	33.5% (190)	33.1% (99)	34.0% (91)	0.908
UA-PDM	32.6% (185)	33.4% (100)	31.7% (85)	
UA-T2DM	33.9% (192)	33.4% (100)	34.3% (92)	
Family history of diabetes				

No family history	20.9% (86)	23.5% (51)	17.9% (35)	0.188
1 st degree family history	41.0% (169)	36.9% (80)	45.6% (89)	
2 nd degree family history	16.7% (69)	18.9% (41)	14.4% (28)	
1 st & 2 nd degree family history	21.4% (88)	20.7% (45)	22.1% (43)	
<hr/>				
No lipid abnormalities	5.0% (28)	5.7% (17)	4.1% (11)	0.386
Lipid abnormalities	95.0% (537)	94.3% (281)	95.9% (256)	
<hr/>				
Vitamin intake (%)				
Non users	92.5% (406)	89.0% (210)	96.6% (196)	0.003
Current users	7.5% (33)	11.0% (26)	3.4% (7)	
<hr/>				
Milk intake (cups/day)	1.68±0.98	1.64±0.97	1.72±0.99	0.410
<hr/>				
Egg intake (eggs/day)	0.58	0.55±0.40	0.60±0.48	0.219

*Percentage (n) or mean values ± SD; *p* value indicates the statistical difference between males and females; **BMI** indicates body mass index; **Underweight** ≤ 18.5 kg/m², **Normal weight** 18.5-24.99 kg/m², **Overweight** 25-29.99 kg/m², **Obese** ≥ 30 kg/m²; **WC** indicates waist circumference; **WHR** indicates waist to hip ratio (waist (cm)/hips (cm)); **SAD** indicates sagittal abdominal diameter in cm; **FPG** indicates fasting plasma glucose; **TG** indicates triglycerides; **HTN** indicates self-reported hypertension and/or use of HTN drugs or systolic ≥140 mmHg or diastolic ≥90 mmHg; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **UA-PDM**: unaware of pre-diabetes (FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **UA-T2DM**: unaware of type 2 diabetes mellitus (FPG ≥7.0 mmol/L; ≥126 mg/dL); **Lipid abnormalities** indicate self-reported dyslipidaemia and/or intake of lipid lowering drugs and/or lipid levels (TC ≥5.2 mmol/L and/or TG ≥1.7 mmol/L and/or LDL-C ≥ 2.6 mmol/L and/or HDL-C <1.03).

Summary

In this section the methods and descriptive results of the dietary biomarkers sample has been presented. In the next section (Chapter 10 - section 1) the results and discussion of the first dietary biomarker (vitamin D) will be presented.

Section 1 Vitamin D and T2DM

Introduction

This section will cover the results and discussion for the association between vitamin D (25 (OH) D) and T2DM. The methods have been presented at the beginning of this chapter (Chapter 10).

10.1.1. Results

A) Sex stratified characteristics across tertiles of 25 (OH) D

Table 10.3. provides the mean levels or percentages of the sub-sample ($n = 567$) sex stratified characteristics across 25 (OH) D tertiles. The mean serum vitamin D concentration in the overall sample was 27.1 nmol/l and for females it was 22.5 nmol/l, and for males it was 33.3 nmol/l.

The mean age increased significantly across tertiles in both females and males. Anthropometric measures (BMI, WC) decreased across tertiles in females, whilst this trend was not observed in males. Education level significantly decreased ($p < 0.001$) across tertiles in females, and the prevalence of higher education was higher in the lowest tertiles of 25 (OH) D. The prevalence of diabetes in females increased across tertiles, 42.2% of females with diabetes were in the highest

tertile whilst 27.8% were in the lowest tertile of 25 (OH) D. A similar, but non-significant, trend was observed in males with diabetes.

The prevalence of HTN increased significantly across tertiles in females; however, there was no linear trend in males. The prevalence of lipid abnormalities increased across tertiles in both males and females; however, this increase was not significant. Mean levels of FPG and TG significantly increased across tertiles in females. On the other hand, a non-significant decrease in mean levels of FPG and TG was observed across tertiles in males.

10.3. Characteristics* stratified by sex across tertiles of 25 (OH) D

Variables	Female				Male			
	I	II	III	<i>p</i>	I	II	III	<i>p</i>
<i>n</i> (%)	33.3% (97)	33.3% (97)	33.3% (97)		33.5% (87)	33.5% (87)	33.5% (87)	
25 (OH) D range (nmol/L)	7.49-15.50	15.52-30.89	31.17-119.10		7.49-27.23	27.24-43.46	43.66-136.19	
25 (OH) D (nmol/L)	10.29±1.29	22.14±1.22	50.60±1.42	<0.001	17.89±1.48	34.08±1.14	60.78±1.33	<0.001
Age (yrs)	37.09±12.908	40.19±14.99	45.89±14.24	<0.001	36.33±15.55	40.83±17.12	44.05±17.13	0.010
BMI (kg/m ²)	31.27±6.78	30.82±6.54	29.18±6.30	0.072	27.49±6.31	28.52±6.08	28.09±5.34	0.531
WC (cm)	94.45±16.76	93.24±15.14	89.44±15.29	0.089	95.66±14.69	96.36±16.10	96.72±15.44	0.912
Education level								
Illiterate	38.5% (35)	44.0% (40)	57.3% (51)	<0.001	9.0% (7)	10.1% (8)	24.1% (19)	0.060
Pre-college	27.5% (25)	31.9% (29)	36.0% (32)		60.3% (47)	58.2% (46)	50.6% (40)	
College or higher	34.1% (31)	24.2% (22)	6.7% (6)		30.8% (24)	31.6% (25)	25.3% (20)	
NDM	38.1% (37)	41.2% (40)	21.6% (21)	0.034	37.9% (33)	32.2% (28)	33.3% (29)	0.813
UA-PDM	34.0% (33)	27.8% (27)	38.1% (37)		33.3% (29)	33.3% (29)	29.9% (26)	
UA-T2DM	27.8% (27)	30.9% (30)	40.2% (39)		28.7% (25)	34.5% (30)	36.8% (32)	
Free from HTN	86.9% (73)	79.8% (71)	70.2% (59)	0.029	77.1% (54)	68.9% (51)	79.2% (57)	
HTN	13.1% (11)	20.2% (18)	29.8% (25)		22.9% (16)	31.1% (23)	20.8% (15)	0.317
No lipid abnormalities	8.3% (8)	5.2% (5)	4.1% (4)	0.431	7.0% (6)	4.6% (4)	1.1% (1)	0.160
Lipid abnormalities	91.7% (88)	94.8% (92)	95.9% (93)		93.0% (80)	95.4% (83)	98.9% (86)	
Physical activity (PA)								
Active	87.8% (79)	84.8% (78)	87.5% (77)	0.806	82.4% (70)	74.1% (63)	76.5% (65)	0.414

Non-active	12.2% (11)	15.2% (14)	12.5% (11)		17.6% (15)	25.9% (22)	23.5% (20)	
PA intensity								
Non-active	12.2% (11)	15.2% (14)	12.5% (11)	0.910	17.6% (15)	25.9% (22)	23.5% (20)	0.548
Not reported	33.3% (30)	27.2% (25)	27.3% (24)		18.8% (16)	20.0% (17)	14.1% (12)	
Mild levels	30.0% (27)	30.4% (28)	35.2% (31)		28.2% (24)	17.6% (15)	29.4% (25)	
Moderate levels (1)	11.1% (10)	8.7% (8)	12.5% (11)		4.7% (4)	8.2% (7)	9.4% (8)	
Moderate levels (2)	12.2% (11)	17.4% (16)	10.2% (9)		14.1% (12)	15.3% (13)	8.2% (7)	
High levels	0.0% (0)	1.1% (1)	1.1% (1)		4.7% (4)	7.1% (6)	4.7% (4)	
Vigorous levels	1.1% (1)	0.0% (0)	1.1% (1)		11.8% (10)	5.9% (5)	10.6% (9)	
Milk intake (cups/day)	1.46±0.90	1.83±1.07	1.56±0.84	0.039	1.62±1.00	1.56±0.79	1.90±1.08	0.086
Egg intake (eggs/day)	0.50±0.34	0.53±0.42	0.63±0.43	0.174	0.55±0.42	0.64±0.56	0.64±0.45	0.483
Systolic (mmHg)	118.17±13.69	118.26±12.45	123.37±15.61	0.023	122.35±14.57	123.89±14.00	120.06±12.26	0.235
Diastolic (mmHg)	76.65±7.09	76.81±8.30	78.67±8.19	0.184	78.82±9.14	79.12±8.49	77.33±7.98	0.400
FPG (mmol/L)	6.51±1.41	6.38±1.31	7.22±1.40	0.019	6.68±1.44	6.73±1.34	6.69±1.29	0.984
Insulin (IU/ml)	15.55±2.35	16.73±2.35	15.49±2.93	0.814	17.91±2.61	19.27±2.98	21.88±2.96	0.447
TC (mmol/L)	5.08±0.99	5.23±1.07	5.34±0.95	0.212	5.16±1.21	5.32±1.42	5.13±1.50	0.627
TG (mmol/L)	2.42±1.35	2.49±1.30	2.68±1.34	0.039	3.01±1.50	3.14±1.46	2.86±1.45	0.298
LDL-C (mmol/L)	3.30±0.84	3.41±0.86	3.45±0.83	0.471	3.24±1.15	3.37±1.22	3.41±1.34	0.679
HDL-C (mmol/L)	1.04±0.34	1.09±0.34	1.00±0.32	0.172	0.77±0.25	0.78±0.32	0.76±0.30	0.887
Se (ng/ml)	102.46±29.78	102.02±32.47	108.82±37.78	0.296	102.83±29.95	106.38±36.84	104.47±39.36	0.813

* Mean values±SD or percentages (n); **BMI** indicates body mass index; **WC** indicates waist circumference; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **UA-PDM**: unaware of pre-diabetes (FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **UA-T2DM**: unaware of type 2 diabetes mellitus (FPG ≥7.0 mmol/L; ≥126 mg/dL); **HTN** indicates self-reported hypertension and/or use of HTN drugs or systolic ≥140 mmHg or diastolic ≥90 mmHg; **Lipid abnormalities** indicate self-reported dyslipidaemia and/or intake of lipid lowering drugs and/or lipid levels (TC ≥5.2 mmol/L and/or TG ≥1.7 mmol/L and/or LDL-C ≥ 2.6 mmol/L and/or HDL-C <1.03); **PA levels**: Mild levels: washing dishes, walking; Moderate (1): table tennis; Moderate (2): brisk walk, High: tennis, volleyball, Vigorous: running, cycling.

B) Correlates of 25 (OH) D levels

Table 10.4. shows Pearson's correlation coefficients between 25 (OH) D levels and covariates for the overall sample ($n = 567$). A significant positive correlation was observed between 25 (OH) D and age ($r = 0.209$). A significant inverse association was observed between BMI and 25 (OH) D ($r = -0.152$), and a similar weaker correlation was observed for WC ($r = -0.057$). Lipid levels were positively correlated with 25 (OH) D, except for HDL-C ($r = -0.135$), however, these associations reached statistical significance for TG and HDL-C only. An inverse correlation was observed between education level and 25 (OH) D ($r = -0.118$).

Table 10.4. Pearson correlation coefficients between 25 (OH) D and covariates for the overall sub-sample

Variable	<i>r</i>	<i>p</i>
Age	0.209	<0.001
BMI	-0.152	<0.001
WC	-0.057	0.203
Systolic	0.079	0.089
Diastolic	0.036	0.432
FPG _{LG}	0.070	0.104
Insulin _{LG}	0.073	0.087
TC	0.033	0.445
TG _{LG}	0.090	0.034
LDL-C	0.066	0.132
HDL-C	-0.135	0.002
Education level	-0.118	0.008
PA	0.068	0.122
Milk intake	0.076	0.108
Egg intake	0.135	0.007

LG indicates logarithmically transformed variables

Sex stratified Pearson correlation coefficients between 25 (OH) D and covariates were further explored (Table 10.5.). A positive significant correlation was observed between age and 25 (OH) D in both females ($r = 0.238$) and males ($r = 0.216$). Inverse associations were observed between anthropometric measures and 25 (OH) D, however, the correlations in females were consistently higher in females for BMI ($r = -0.134$) and WC ($r = -0.155$) in comparison to males. Significant positive correlations were observed in females for both FPG ($r = 0.165$) and TG ($r = 0.150$). Although an inverse correlation between 25 (OH) D and education level was observed in both females and males, the correlation was higher amongst females ($r = -0.245$). A significant positive correlation between egg intake and serum levels was observed in females ($r = 0.183$).

Table 10.5. Sex stratified correlations between 25 (OH) D and covariates

Variable	Females		Males	
	<i>r</i>	<i>p</i>	<i>r</i>	<i>p</i>
Age	0.238	<0.001	0.216	<0.001
BMI	-0.134	0.023	-0.054	0.393
WC	-0.155	0.012	-0.021	0.751
Systolic	0.136	0.029	-0.062	0.370
Diastolic	0.089	0.157	-0.078	0.254
FPG _{LG}	0.165	0.005	-0.059	0.348
Insulin _{LG}	0.051	0.385	0.039	0.532
TC	0.100	0.088	-0.025	0.684
TG _{LG}	0.150	0.010	-0.108	0.082
LDL-C	0.079	0.187	0.080	0.215
HDL-C	-0.047	0.432	0.020	0.752
Education level	-0.245	<0.001	-0.105	0.108
PA	0.016	0.799	0.043	0.498
Milk intake	0.038	0.596	0.108	0.115
Egg intake	0.183	0.008	0.051	0.489

LG indicates log transformed variables.

C) Interaction between 25(OH) D and covariates (age and BMI)

Table 10.6. shows the interaction between serum 25(OH)D, BMI and age. The interaction between age and 25 (OH) D levels did not achieve statistical significance in the overall sample or in females, however, it was significant in males ($p=0.021$). A test of interaction between 25(OH) D levels and BMI did not achieve statistical significance. Since there was an interaction between age and 25(OH)D₃ in males, we further explored the prevalence of diabetes in groups split by the median of age (Table 10.8). However, there was no significant difference in both groups (above and below the median age). Hence, no further stratification was carried out in univariate analysis (Table 10.9.).

Table 10.6. Testing for interaction between 25 (OH) D and age

Sample	<i>p</i> value
Overall sample	0.052
Females	0.652
Males	0.021
Model summery: 25(OH) D plus age plus age*25(OH) D; <i>p</i> value indicates the statistical significance of interaction.	

Table 10.7. Testing for interaction between 25(OH) D and BMI

Sample	<i>p</i> value
Overall sample	0.611
Females	0.188
Males	0.131
Model summery: 25(OH) D plus BMI plus BMI*25(OH) D, <i>p</i> value indicates the statistical significance of interaction.	

Table 10.8. Prevalence* of diabetes across 25(OH)D in males (by the median of age)

% DM	≤ 38				>38			
	I	II	III	<i>p</i>	I	II	III	<i>p</i>
NDM	48.1% (26)	32.6% (15)	34.3% (12)		21.2% (7)	31.7% (13)	32.7% (17)	
UA-PDM	29.6% (16)	37.0% (17)	37.1% (13)	0.551	39.4% (13)	29.3% (12)	25.0% (13)	0.645
UA-T2DM	22.2% (12)	30.4% (14)	28.6% (10)		39.4% (13)	39.0% (16)	42.3% (22)	

*Percentage (n); **NDM**: non diabetics (FPG < 6.1 mmol/L; <110 mg/dL), **UA-PDM**: unaware of pre-diabetes (FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **UA-T2DM**: unaware of type 2 diabetes mellitus (FPG ≥7.0 mmol/L; ≥126 mg/dL)

D) Mean levels of 25(OH)D and diabetes

The adjusted mean values of serum 25(OH)D are presented in Table 10.9. In the overall sample, participants with diabetes had higher levels of serum 25(OH)D in comparison to other groups (NDM and PDM). The sex stratified analysis showed that females with diabetes had higher levels of serum 25(OH)D in comparison to non-diabetics and pre-diabetics. These levels remained significantly higher in the fully-adjusted model in females. However, that was not the case in males. The non-diabetes group had higher levels of serum 25(OH)D levels in comparison to the diabetes and pre-diabetes group, but the increase did not reach statistical significance.

Table 10.9. Analysis of mean levels of 25(OH)D across diabetes groups (95% CI)

Overall sample

Model	NDM ± SEM	UA-PDM ± SEM	UA-T2DM ± SEM	<i>p</i>
Model 1	25.29±1.49	26.66±1.05	29.78±1.05	0.062
Model 2	25.23±1.04	26.73±1.04	29.72±1.04	0.048
Model 3	26.30±1.04	26.85±1.04	28.37±1.04	0.515
Model 4	25.29±1.04	26.48±1.04	28.70±1.04	0.175

NDM indicates non-diabetics, **UA-PDM** indicates unaware of pre-diabetes, **UA-T2DM** indicates unaware of type 2 diabetes; **SEM** indicates standard error of mean values; *p* value indicates statistical difference between groups; **Model summary**: Model 1: Unadjusted, Model 2: Sex adjusted, Model 3: as previous plus age, Model 4: as previous plus BMI

Females

Model	NDM \pm SEM	UA-PDM \pm SEM	UA-T2DM \pm SEM	<i>p</i>
Model1	19.05 \pm 1.07	23.01 \pm 1.07	26.36 \pm 1.07	0.005
Model2	20.23 \pm 1.07	22.90 \pm 1.07	25.06 \pm 1.07	0.113
Model3	19.09 \pm 1.07	22.59 \pm 1.06	25.41 \pm 1.07	0.018

Males

Model	NDM \pm SEM	UA-PDM \pm SEM	UA-T2DM \pm SEM	<i>p</i>
Model1	34.43 \pm 1.06	31.55 \pm 1.06	33.96 \pm 1.06	0.576
Model2	35.39 \pm 1.06	31.98 \pm 1.06	32.65 \pm 1.06	0.470
Model3	34.91 \pm 1.06	31.55 \pm 1.06	32.88 \pm 1.06	0.503

NDM indicates non-diabetics, **UA-PDM** indicates unaware of pre-diabetes, **UA-T2DM** indicates unaware of type 2 diabetes; **SEM** indicates standard error of mean values; ***p*** value indicates statistical difference between groups; **Model summary**: Model 1: Unadjusted; Model 2: adjusted for age; Model 3: Adjusted as previous plus BMI.

10.1.2. Discussion

In this section the association between dietary biomarkers (vitamin D) and T2DM were presented for a random sub-sample ($n = 567$) of the projects original cohort ($n = 2631$). Despite the hot weather in Saudi Arabia and the availability of sunshine throughout the year (Nofal and Saeed 1997), an important source for vitamin D synthesis (Dawson-Hughes et al. 1997), the mean levels of 25 (OH) D in the overall sample were very low, at 27.16 nmol/l. The mean levels of this study are comparable to earlier observations from Saudi Arabia. For example, studies showed that 25 (OH) D concentrations were very low in Saudi individuals, in 104 Saudi male adults, mean levels of serum 25 (OH) D were 32.0 nmol/l (Sedrani 1984). Levels were lower in 139 Saudi

healthy adults living in the Eastern region, where mean levels of 25 (OH) D were 25.0 nmol/l (Elsammak et al. 2011).

Saudi adults have lower vitamin D concentrations in comparison to other Gulf and Middle Eastern countries. For instance, in Qatar, mean levels of 25 (OH) D were 29.25 nmol/l in adults (Mahdy et al. 2010). Iranian adults had higher vitamin D levels in comparison to Gulf countries, where mean serum vitamin D concentrations were 32.48 nmol/l in 1210 Iranian adults (Hashemipour et al. 2006). Western populations have higher vitamin D levels in comparison to Middle Eastern countries (Mithal et al. 2009). The French SUVIMAX study which included 1569 adults from 20 different cities, found that the mean levels of vitamin D were 61 nmol/l (Chapuy et al. 1997). Similar levels were observed in the US; the NHANES 2001-2004 study found that mean levels of vitamin D are around 60 nmol/l in American adults (Ginde et al. 2009).

There are several factors that may play a role behind the low levels of vitamin D observed in Saudi adults. Saudi Arabia is a sun-flooded country, however, the atmosphere is saturated with dust particles which may insulate sunlight absorption. The Saudi traditional dress code in both males and females cover all body parts except for the face and hands, and this may also contribute to the decreased absorption of sunlight (Sedrani et al. 1983). In addition, the very hot temperatures in Saudi Arabia prevent people from engaging in outdoor activities. Saudis spend most of the time indoors and cars are widely used for short-distance travel (El-Hazmi et al. 1997).

The skin colour of Saudi individuals may also play a role in the decreased synthesis of vitamin D (Elsammak et al. 2011), because it has been reported that vitamin D synthesis is impaired because of skin pigmentation (Bell et al. 1985). Researchers suggested that lack of food fortification is associated with low vitamin D levels in Saudi individuals (Sedrani 1984, AL-Daghri et al. 2010). Although milk and egg intake were the only available dietary sources of vitamin D in this study, the results showed that both milk and egg intake increased across vitamin D tertiles and showed a positive association with vitamin D levels. This suggests that dietary intake may affect vitamin D levels in Saudi individuals but warrants further investigation.

Studies have shown that higher education is associated with increased vitamin D levels (Holick et al. 2005, Kilkkinen et al. 2009), however this may not be applicable to Saudi adults. The results showed that higher education levels decreased across tertiles of vitamin D. Saudis with higher education are more likely to engage in indoor professions which decrease sun exposure. In Qatar, the majority of health care professionals with low vitamin D levels reported less time spent in the sun and more time spent indoors (Mahdy et al. 2010).

In this study, females had significantly lower vitamin D levels (22.59 nmol/l) than males (33.35 nmol/l), and this trend has been previously reported in Saudi Arabia (Alsuwaida et al. 2013). Neighbouring countries report similar findings, in 340 adults living in Qatar, females had lower levels (25.75 nmol/l) in comparison to males (34.25 nmol/l) (Mahdy et al. 2010), and similar levels have been observed in 259 Emirati females (25.3 nmol/l) (Saadi et al. 2006). In 1111

healthy Iranian adults, females had significantly lower levels (45 nmol/l) in comparison to males (52.5 nmol/l) (Hovsepian et al. 2011), and a similar trend was found in 316 Lebanese adults (Gannagé-Yared et al. 2000). In Tunisian adults, levels of 25 (OH) D ranged from 35.07 nmol/l in veiled women to 42.5 nmol/l in unveiled women (Meddeb et al. 2005).

The sex difference in vitamin D levels has also been reported in westernized countries. In the SENECA study, which included 12 European countries, 47% of females had vitamin D levels below 30 nmol/l in comparison to 36% of males (van der Wielen et al. 1995). Findings from the NHANES III showed that females had lower vitamin D concentrations (69.8 nmol/l) in comparison to males (77.4 nmol/l) (Martins et al. 2007). Similarly in New Zealand, vitamin D levels were lower amongst females (51 nmol/l) in comparison to males (85 nmol/l). Nevertheless, the results of this study showed that Saudi adults, especially females, have lower vitamin D levels in comparison to other Middle Eastern and westernized countries.

There are several cultural and lifestyle factors that may contribute to the poor vitamin D status in Saudi females; multiple pregnancies and longer durations of breastfeeding can negatively affect vitamin D levels (Ghannam et al. 1999), and parity was found to be associated with lower vitamin D levels in Lebanese females (Gannagé-Yared et al. 2000). The Saudi culture and lifestyle restrict females from engaging in outdoor activities, and females spend most of their time indoors (El-Hazmi and Warsy 1997). There are very few outdoor facilities for Saudi females (Alsaif et al. 2002) and this may lead to less sun exposure and

eventually lower vitamin D levels. The womens dress code in Saudi Arabia (*veil or niqab*) may also contribute to the low vitamin D levels amongst females (Elsammak et al. 2011). Studies have shown that veiled women have lower vitamin D levels in comparison to non-veiled women (el-Sonbaty et al. 1996, Gannagé-Yared et al. 2000, Meddeb et al. 2005).

Obesity may also play a role behind the lower levels observed amongst females. Adiposity decreases the bioavailability of vitamin D because of excess vitamin D storage in adipose tissues (Wortsman et al. 2000). In this study, obesity measures (BMI and WC) were inversely associated with vitamin D levels. A stronger inverse association was observed amongst females in comparison to males, and this may be attributed to the higher prevalence of obesity among females. On the other hand, poor vitamin D status may play a role in the high obesity prevalence observed in Saudi females. Studies have suggested that low vitamin D levels may promote weight gain as a result of elevated parathyroid hormone levels which increase lipogenesis (Snijder et al. 2005, van Dam et al. 2007). Nevertheless, the inverse association between adiposity and low vitamin D levels observed in this study is consistent with previous international reports (Snijder et al. 2005, van Dam et al. 2007, Konradsen et al. 2008, McGill et al. 2008).

Although previous studies have shown that serum vitamin D levels are lower in diabetics in comparison to non-diabetics (Scragg et al. 1995, Yoho et al. 2009), this may not be the case within the Saudi context. The results showed that non-diabetics had lower levels of 25 (OH) D in comparison to adults with glucose abnormalities (25.29 vs. 28.18 nmol/l, respectively). This difference has been

reported in a previous observational study conducted in Saudi Arabia. In 177 non diabetic Saudi adults the mean levels of vitamin D were lower in comparison to 164 type 2 diabetics (17.9 nmol/l vs. 26.9 nmol/l) (AL-Daghri et al. 2010). However, the study included participants with diagnosed diabetes. In Saudi Arabia, multivitamin supplementation is part of the treatment plan for type 2 diabetes, and this may explain the higher levels observed in T2DM participants (AL-Daghri et al. 2010). The latter is not applicable to this study because participants with T2DM were unaware of their condition, therefore they were not on any diabetes treatment plan. A sensitivity analysis was conducted to exclude participants who reported a current intake of multivitamins, and the results showed that vitamin D levels remained higher in participants with glucose abnormalities (30.36 nmol/l in T2DM, 27.16 nmol/l in PDM, and 25.17 nmol/l in NDM). A possible explanation is the strong association observed between vitamin D levels and age in this study which was stronger amongst females. Participants with T2DM are significantly older than non-diabetics, and although skin synthesis of vitamin D declines with age, this does not affect the concentrations of 25(OH)D (Harris et al. 2000). However, the metabolic clearance of 25(OH)D declines with age because of a decline in kidney function (Vieth et al. 2003). Nevertheless, these observations are in agreement with other reports on vitamin D levels in older adults. In 1210 Iranian adults, higher vitamin D levels were observed in older adults compared to younger Iranians (Hashemipour et al. 2004). Other international observations have also found that vitamin D levels are not lower in older individuals (Harris et al. 2000, Tangpricha et al. 2002, Vieth et al. 2003). The levels of vitamin D were higher amongst older US adults in comparison to younger adults (Tangpricha et al.

2002). In a Canadian study, Veith *et al.* found that vitamin D levels in 1741 participants were not lower in older participants (Vieth et al. 2003). In addition to the significant correlation observed between age and vitamin D levels, osteoporosis therapy may also explain this difference, because pharmacological treatment for this condition may boost vitamin D status amongst women (Sambrook et al. 2002). The prevalence of osteoporosis amongst Saudi females is extremely high and ranges from 50-70% (Sadat-Ali et al. 2004). Osteoporosis was not assessed in the original survey (2009), therefore, the misreports in osteoporosis therapy might contribute to the higher vitamin D levels amongst diabetic females.

Culturally specific cut-offs for vitamin D deficiency are not available in Saudi Arabia, and studies have used different thresholds to define vitamin D deficiency (Al Faraj and Al Mutairi 2003, AL-Daghri et al. 2010, Elsammak et al. 2011). A recent review defined vitamin D deficiency if 25(OH)D concentrations were ≤ 25 nmol/l (Thacher et al. 2011). According to these values, the overall sample suffers from vitamin D deficiency, and females in the highest tertile are vitamin D insufficient. This highlights the magnitude of the problem, especially amongst Saudi females.

Summary

In this section the association between vitamin D and T2DM was presented. Analysis was presented for the overall sample and stratified by sex. In the next section (Chapter 10 – section 2), the second biomarker of nutritional status (Se)

will be presented. The Se section will include the results and discussion on the association between Se and T2DM.

Section 2 Selenium and T2DM

Introduction

This section will cover the results and discussion on the association between Se and T2DM. The methods were presented at the beginning of this chapter (Chapter 10).

10.2.1. Results

A) Sex-specific characteristics across tertiles of selenium

Table 10.10 provides the mean levels or percentages of the sub-sample ($n = 567$) characteristics across sex-specific tertiles of serum Se levels. The mean serum selenium concentration in the overall sample was 104.3 ng/ml. There was an equal distribution of the sample across tertiles in both females (33.1%) and males (33.5%). Obesity measures, such as BMI and WC, increased across Se tertiles. A significant increase in BMI was observed in females, and a similar non-significant trend was observed in males. There was a linear increase in the prevalence of diabetes across Se tertiles in both females and males, however, this increase did not reach significance. Similarly, systolic blood pressure, diastolic blood pressure and the prevalence of hypertension increased across serum Se tertiles but did not reach a conventional level of statistical significance. There

was a non-significant increase in FPG in both females and males across tertiles, and an increase in fasting insulin. However, lipid levels increased with higher serum Se levels in both sexes, mean TC and LDL-C levels increased across tertiles ($p < 0.05$). Mean levels of TG increased significantly ($p = 0.018$), whilst HDL-C decreased significantly across tertiles in females.

B) Correlates of serum Se

Table 10.11. shows the Pearson's correlation coefficients between serum selenium levels and covariates of the overall sample ($n = 567$). The majority of covariates had a positive correlation with serum Se except for an inverse correlation between HDL-C and education levels. Generally, the associations were weak between serum Se and covariates, and the majority of covariates did not reach a conventional level of statistical significance ($p < 0.05$), except for TG and insulin. A significant positive correlation was observed between TG ($r = 0.124$) fasting insulin ($r = 0.110$) and serum Se. However, sex stratification improved the correlations, mainly in females, as shown in table 10.12. Diastolic blood pressure showed a positive significant correlation with Se ($r = 0.140$). Generally, lipid profile parameters in females showed a significant correlation with serum selenium such as TC ($r = 0.160$), TG ($r = 0.141$), and LDL-C ($r = 0.146$). In males, the majority of associations did not reach statistical significance except for fasting insulin ($r = 0.134$) and TG that reached borderline significance ($r = 0.116$).

Table 10.10. Sex-specific characteristics* across tertiles of serum Se

Variables	Female				Male			
	I	II	III	<i>p</i>	I	II	III	<i>p</i>
n (%)	97 (33.3%)	97 (33.3%)	97 (33.3%)		82 (33.1%)	83 (33.5%)	83 (33.5%)	
Se range (ng/ml)	16.99-88.19	88.47-113.88	114.87-232.92		16.82-89.90	90.19-114.45	114.57-234.35	
Se (ng/ml)	68.92±18.31	101.38±7.14	142.07±24.76	<0.001	70.34±18.50	100.92±7.45	141.92±27.42	<0.001
Age (yrs)	40.81±15.63	40.09±14.21	41.36±13.62	0.830	40.05±19.56	40.11±14.31	41.23±17.44	0.884
BMI (kg/m²)	28.91±5.81	31.76±7.32	30.65±6.48	0.012	27.28±5.43	28.79±6.06	28.18±28.18	0.265
WC (cm)	91.48±16.37	91.98±15.94	92.86±15.66	0.846	93.96±14.79	99.62±15.11	95.12±15.91	0.059
Education level								
Illiterate	46.7% (43)	42.4% (39)	47.2% (42)	0.899	18.9% (14)	12.3% (9)	14.3% (11)	0.608
Pre-college	30.4% (28)	37.0% (34)	31.5% (28)		50.0% (37)	56.2% (41)	61.0% (47)	
College or higher	22.8% (21)	20.7% (19)	21.3% (19)		31.1% (23)	31.5% (23)	24.7% (19)	
Diabetes (%)								
NDM	33.0% (32)	30.9% (30)	35.1% (34)	0.480	42.7% (35)	30.1% (25)	32.5% (27)	0.285
UA-PDM	39.2% (38)	34.0% (33)	27.8% (27)		29.3% (24)	39.8% (33)	30.1% (25)	
UA-T2DM	27.8% (27)	35.1% (34)	37.1% (36)		28.0% (23)	30.1% (25)	37.3% (31)	
Hypertension								
Non hypertensive	81.5% (66)	75.9% (66)	79.5% (70)	0.661	77.9% (53)	74.6% (50)	71.8% (51)	0.709
Hypertensive	18.5% (66)	24.1% (21)	20.5% (18)		22.1% (15)	25.4% (17)	28.2% (20)	
No lipid abnormalities	8.2% (8)	4.2% (4)	4.1% (4)	0.353	4.9% (4)	3.6% (3)	4.9% (4)	0.902
Lipid abnormalities	91.8% (89)	95.8% (92)	95.9% (93)		95.1% (78)	96.4% (80)	95.1% (78)	
Physical activity (PA)								

Active	85.2% (75)	90.0% (81)	88.0% (81)	0.621	83.3% (65)	74.4% (61)	73.5% (61)	0.265
Non-active	14.8% (13)	10.0% (9)	12.0% (11)		16.7% (13)	25.6% (21)	26.5% (22)	
PA intensity								
Non-active	14.8% (13)	10.0% (9)	12.0% (11)	0.844	16.7% (13)	25.6% (21)	26.5% (22)	0.012
Not reported	34.1% (30)	27.8% (25)	28.3% (26)		26.9% (21)	4.9% (4)	19.3% (16)	
Mild levels	31.8% (28)	31.1% (28)	31.5% (29)		19.2% (15)	31.7% (26)	26.5% (22)	
Moderate levels (1)	8.0% (7)	11.1% (10)	14.1% (13)		9.0% (7)	6.1% (5)	6.0% (5)	
Moderate levels (2)	11.4% (10)	16.7% (15)	12.0% (11)		9.0% (7)	17.1% (14)	10.8% (9)	
High levels	0.0% (0)	2.2% (2)	1.1% (1)		10.3% (8)	2.4% (2)	4.8% (4)	
Vigorous levels	0.0% (0)	1.1% (1)	1.1% (1)		9.0% (7)	12.2% (10)	6.0% (5)	
Systolic (mmHg)	118.05±14.23	120.83±15.08	120.85±13.26	0.346	121.82±11.56	121.91±14.45	122.51±12.53	0.943
Diastolic (mmHg)	76.20±8.05	76.86±7.92	78.76±7.48	0.086	77.69±7.67	78.88±7.42	78.63±9.11	0.668
FPG (mmol/L)	6.60±1.34	6.64±1.36	6.89±1.43	0.607	6.56±1.34	6.73±1.31	6.72±1.39	0.838
Fasting insulin (IU/ml)	14.99±2.68	16.28±2.72	16.99±2.23	0.632	16.12±2.86	23.24±2.50	19.19±3.11	0.083
TC (mmol/L)	5.14±0.95	5.10±1.09	5.48±1.19	0.027	5.00±1.26	5.53±1.38	5.07±1.32	0.019
TG (mmol/L)	2.44±1.29	2.47±1.36	2.73±1.36	0.018	2.85±1.49	3.13±1.45	1.45±3.06	0.265
LDL-C (mmol/L)	3.34±0.81	3.30±0.93	3.61±1.00	0.046	3.14±1.13	3.70±1.24	3.23±1.17	0.007
HDL-C (mmol/L)	1.10±0.36	1.03±0.35	0.97±0.29	0.040	0.81±0.35	0.72±0.27	0.76±0.24	0.161
25(OH)D (nmol/L)	22.04±1.97	21.54±2.08	23.72±2.02	0.451	33.05±1.82	32.43±1.78	33.13±1.72	0.967

*Mean values ±SD or percentages (n); **BMI** indicates body mass index; **WC** indicates waist circumference; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **UA-PDM**: unaware of pre-diabetes (FPG 6.1 - 6.9 mmol/L, 110 to 125 mg/dL), **UA-T2DM**: unaware of type 2 diabetes mellitus (FPG ≥ 7.0 mmol/L; ≥ 126 mg/dL); **HTN** indicates self-reported hypertension, or use of HTN drugs or systolic ≥ 140 mmHg or diastolic ≥ 90 mmHg; **Lipid abnormalities** indicate self-reported dyslipidaemia or intake of lipid lowering drugs or lipid levels (TC ≥ 5.2 mmol/L and/or TG ≥ 1.7 mmol/L and/or LDL-C ≥ 2.6 mmol/L and/or HDL-C < 1.03); **PA levels**: Mild levels: washing dishes, walking; Moderate (1): table tennis; Moderate (2): brisk walk, High: tennis, volleyball, Vigorous: running, cycling;

Table 10.11. Pearson correlation coefficients between Se and covariates for the overall sub-sample

Variable	<i>r</i>	<i>p</i>
Age	0.028	0.518
BMI	0.067	0.123
WC	0.039	0.390
Systolic	0.056	0.231
Diastolic	0.074	0.112
FPG_{LG}	0.049	0.259
Insulin_{LG}	0.110	0.011
TC	0.073	0.091
TG_{LG}	0.124	0.004
LDL-C	0.051	0.249
HDL-C	-0.072	0.101
25 (OH) D_{LG}	0.49	0.267
Education level	-0.049	0.271
PA	0.023	0.597
KCAL_{LG}	0.017	0.700

LG indicates logarithmically transformed variables.

Table 10.12. Sex stratified correlations between Se and covariates

Variable	Females		Males	
	<i>r</i>	<i>p</i>	<i>r</i>	<i>p</i>
Age	0.026	0.653	0.030	0.643
BMI	0.089	0.131	0.044	0.501
WC	0.047	0.444	0.031	0.646
Systolic	0.097	0.123	0.005	0.938
Diastolic	0.140	0.026	0.002	0.973
FPG_{LG}	0.083	0.159	0.008	0.905
Insulin_{LG}	0.086	0.149	0.134	0.035
Cholesterol	0.160	0.006	-0.009	0.883
TG_{LG}	0.141	0.016	0.116	0.070
LDL-cholesterol	0.146	0.014	-0.038	0.567
HDL-cholesterol	-0.100	0.093	-0.045	0.497
25 (OH) D_{LG}	0.098	0.098	-0.016	0.809
Education level	-0.046	0.434	-0.060	0.372
PA	0.074	0.224	-0.030	0.638

KCAL_{LG}	0.031	0.600	-0.001	0.986
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LG indicates logarithmically transformed variables.

C) Interaction between serum Se levels and covariates (age and BMI)

Tables 10.13. and 10.14. show the interaction between Se levels and covariates (age and BMI) for the overall sample and sex-stratified interactions. None of these interactions achieved a conventional level of statistical significance ($p < 0.05$). Hence, no further stratification was carried out.

Table 10.13. Testing for interaction between serum selenium and age

Model	<i>p</i> value
Overall sample	0.881
Females	0.764
Males	0.816

Model summary: serum selenium plus age plus age*serum selenium.

Table 10.14. Testing for interaction between serum selenium and BMI

Model	<i>p</i> value
Overall sample	0.825
Females	0.427
Males	0.546

Model summary: serum selenium plus BMI plus BMI*serum selenium.

D) Mean levels of serum Se across diabetes groups

Mean levels of serum Se increased across diabetes groups, participants with diabetes had higher levels of Se in comparison to non-diabetics and pre-diabetics (Table 10.15.). There was no significant difference in mean levels across groups and this did not change in the fully-adjusted

model. In general, females had higher levels of serum Se in comparison to males. Similarly to the overall sample, females and males with diabetes had higher levels of serum selenium in comparison to other groups.

Table 10.15. Analysis of mean levels of serum Se across diabetes groups (95% CI)

Overall sample

Model	NDM±SEM	UA-PDM±SEM	UA-T2DM±SEM	<i>p</i>
Model 1	103.47 ± 2.55	102.93 ± 2.57	107.45 ± 2.60	0.404
Model 2	103.46 ± 2.55	102.94 ± 2.57	107.46 ± 2.60	0.404
Model 3	103.59± 2.59	102.95± 2.57	107.32± 2.65	0.789
Model 4	104.76± 2.64	103.12± 2.62	107.19± 2.69	0.554

NDM indicates non-diabetics, PDM indicates pre-diabetics, T2DM indicates type 2 diabetics; SEM indicates standard error of mean values; *p* value indicates statistical difference between groups; **Model summary:** Model 1: unadjusted, Model 2: sex adjusted, Model 3: as previous plus age; Model 4: as previous plus BMI.

Females

Model	NDM±SEM	UA-PDM±SEM	UA-T2DM±SEM	<i>p</i>
Model 1	104.53 ± 3.48	101.36± 3.44	107.91 ± 3.46	0.408
Model 2	104.65 ± 3.58	101.35 ± 3.45	107.80 ± 3.56	0.429
Model 3	105.55± 3.62	101.42± 3.46	108.04 ± 3.57	0.401

Males

Model	NDM±SEM	UA-PDM±SEM	UA-T2DM±SEM	<i>p</i>
Model 1	102.30 ± 3.77	104.82 ± 3.88	106.89 ± 3.95	0.701
Model 2	102.42± 3.80	104.86 ± 3.89	106.71 ± 4.02	0.742
Model 3	103.80 ± 3.90	105.26 ±4.02	106.21 ±4.12	0.941

NDM indicates non-diabetics, UA-PDM indicates unaware of pre-diabetes, UA-T2DM indicates unaware of type 2 diabetics; SEM indicates standard error of mean values; *p* value indicates statistical difference between groups; **Model summary:** Model 1: unadjusted, Model 2: age adjusted, Model 3: age and BMI adjusted.

10.2.2. Discussion

In this section the association between serum selenium and T2DM were presented for a random sub-sample ($n = 567$) of the projects original cohort ($n = 2631$). In Saudi Arabia

dietary Se intake is around 75–122 µg/person/day (Al-Ahmary 2009). The mean levels of Se selenium in 743 healthy Saudi adults were 107.04 µg/l (Al-Saleh et al. 2007), and these levels are comparable to the mean levels of this study sample (104.35 ng/ml). Mean levels of serum selenium in Saudi adults are comparable to countries with high selenium status such as the Lebanon (142 ng/ml) (Obeid et al. 2008), US (125.7 ng/ml) (Bleys et al. 2008), Canada (115 ng/ml) (Gibson et al. 1985), and Japan (107 ng/ml) (Imai et al. 1990). Therefore Saudi adults should also be considered as a selenium-replete population, similar to North-American countries, likely as a result of the amount of selenium in the soil and hence in natural foods, rather than as a result of fortification or intake of selenium-containing supplements. Findings from international studies have suggested an association between high selenium status and several chronic conditions (Rees et al. 2013), such as diabetes (Stranges et al. 2010), hypertension (Laclaustra et al. 2009), and adverse lipid profile (Stranges et al. 2010). Although Saudi individuals have a high Se status, the association between Se and disease has not been extensively studied within the Saudi context.

Some observational studies have reported a sex-specific difference in Se concentrations, where males had higher levels than females (Kafai et al. 2003, Laclaustra et al. 2009). In this study, there were no sex-specific differences in Se concentrations (104.59 ng/ml in both females and males). Although vitamin supplements intake was low in the overall sample (7.5%), females reported a higher use of supplements than males (11% vs. 3.4%). Another possible explanation is that Saudi females consumed high amounts of dietary selenium. Studies from the Middle East have reported controversial observations on the difference in Se status in males and females. In Kuwaiti adults there was no significant difference in Se levels between males (87.4 µg/l) and females (87.6 µg/l) (Al-Sayer et al. 2000). On the other hand, Iranian females (93.9 µg/l) had significantly

lower selenium levels in comparison to Iranian males (102.2 µg/l) (Safaralizadeh et al. 2005). Nevertheless, Saudi females have higher selenium concentrations in comparison to Kuwaiti (Al-Sayer et al. 2000), Iranian (Safaralizadeh et al. 2005), and Turkish (Coskun et al. 2013) females. Lebanese adults seem to have the highest Se concentrations in the Middle Eastern region. In 398 Lebanese adults, Se concentrations were higher in males (151.2 ng/ml) in comparison to females (135 ng/ml) (Obeid et al. 2008).

Earlier observational studies have shown an inverse association between age and Se concentrations (Swanson et al. 1990, Jossa et al. 1991, Olivieri et al. 1994, Coudray et al. 1997). The results of this study have shown a gradual increase in age across selenium tertiles, and a positive correlation between Se levels and age but neither reached statistical significance. Neighbouring countries, such as Iran (Safaralizadeh et al. 2005), and the Lebanon have found similar associations (Obeid et al. 2008). Similarly, international observations have reported a positive association between Se levels and age (Bleys et al. 2007, Bleys et al. 2008, Laclaustra et al. 2009, Laclaustra et al. 2010).

Although it has been suggested that obesity is associated with lower nutrient levels (Kimmons et al. 2006), this may not be the case for Se levels in Saudi Arabia. Obesity measures, such as BMI and WC, were associated with higher selenium levels in this sample. This may indicate the high consumption of dietary Se in Saudi adults. In Riyadh, where this study was conducted, dietary Se intake was around 90 µg/person/day, and the main sources were cereals and cereal products, meat and eggs (Al-Othman et al. 2012). Over-nourishment in Saudi adults may play a role in the association between Se levels and obesity measures. In fact, it is plausible that high-selenium status may well represent a marker of over-nutrition (Al-Othman et al. 2012).

International evidence has suggested an association between high Se status and diabetes (Bleys et al. 2007, Stranges et al. 2007, Laclaustra et al. 2009). In this study, both females and males with diabetes had the highest levels of serum Se. Diabetes markers (FPG, and fasting insulin) and the prevalence of diabetes increased across Se tertiles, however this did not reach statistical significance. The association between Se levels and chronic conditions has not been extensively explored in the Middle Eastern region. One study in Saudi Arabia has examined urinary Se in 340 adults (diabetics and non-diabetics). Although there was no difference in Se levels between diabetic and non-diabetics, urinary Se was significantly associated with HbA1c levels in Saudi adults (El-Yazigi et al. 1996). In 398 Lebanese adults, serum Se levels were significantly associated with glucose levels (Obeid et al. 2008).

The findings of this study have shown a significant association between fasting insulin and serum Se in the overall sample ($r = 0.111$, $p = 0.011$) and in males ($r = 0.134$, $p = 0.034$). International studies have reported an association between insulin resistance and high Se levels (Chen et al. 2003, Stranges et al. 2007). Furthermore, Chen *et al.* have reported an association between insulin resistance and glutathione peroxidase activity in 408 non-diabetic women during pregnancy (Chen et al. 2003).

The results of this study have shown an association between lipid abnormalities and serum selenium, and the association was stronger in females in comparison to males. All lipid parameters (TC, TG, LDL-C, and HDL-C) clearly increased across Se tertiles in females. In addition, significant correlations were observed between TC, TG, LDL-C and Se levels. The results of this study are in line with other observational studies from Saudi Arabia. In 140 Saudi males, urinary Se was significantly associated with TC and LDL-C levels. Although serum Se was measured in the study, the associations between

serum Se and lipid parameters were not explored (Alissa et al. 2008). Similarly, serum Se levels were significantly associated with LDL-C levels in Lebanese adults (Obeid et al. 2008). The findings of this study parallel international cross-sectional studies suggesting that high Se concentrations are associated with adverse lipid profile. For example, in the NHANES study the prevalence of hypercholesteremia increased significantly across Se quintiles (Bleys et al. 2007), and serum Se was associated with increased TC, TG, and LDL-C concentrations (Bleys et al. 2008, Laclaustra et al. 2010). In the UK, higher Se levels were associated with elevated TC concentrations (Stranges et al. 2010). In France, the EVA (Epidemiology of Vascular Aging) study, Se concentrations were associated with TC and LDL-C amongst males (Coudray et al. 1997). The findings have shown that Saudi adults have high Se concentrations, and individuals with diabetes had the highest levels. High Se concentrations in Saudi individuals may be associated with an adverse lipid profile. However, the potential of reverse causation cannot be ruled out to explain these findings, given the cross-sectional design of our study. In fact, recent findings from a RCT do not support potential adverse effect of selenium supplementation on blood lipids, at least in populations with suboptimal selenium status (Rayman et al. 2011).

Summary

In this chapter the third section on the associations between surrogate markers of nutritional status (vitamin D and selenium) and T2DM were presented. Analysis was presented for the overall sample and stratified by sex. In the next chapter (Chapter 10), the cultural barriers to healthy eating and T2DM will be presented. The first section will cover the methods and lessons learnt from the pilot study, and the second section will cover the methods, results and discussion.

11 Cultural barriers to healthy eating in Saudi adults with and without T2DM

Introduction

This chapter consists of two sections, the pilot study of the cultural barriers to healthy eating questionnaire which was developed specifically for this study and two pre-developed questionnaires that were modified in this study (section one), and the cultural barriers to healthy eating in T2DM study (section two). In the first section, the methods and lessons learnt from the pilot study are presented for a sample of 30 primary health care centres (PHCC's) attendees. In the second section, the cultural barriers to healthy eating in T2DM are presented for a subsample ($n = 108$) of the original Biomarkers Screening in Riyadh (BSR) sample ($n = 2631$), with analyses stratified by sex and diabetes status.

11.1. Rational

The Arab cultural, social, and lifestyle patterns are very different to those in western societies (Lipson and Meleis 1983). The Saudi culture has some unique features such as strong Islamic beliefs, cultural constraints that prevent people in engaging in physical activities (Rawas et al. 2012), and frequent social events accompanied by large amounts of food (Al-Othaimen et al. 2007). Poor dietary knowledge is prevalent among Saudi Adults (Bani and Hashim 1999, Abahussain and El-Zubier 2005, Al-Gelban 2008), accompanied by cultural barriers that prevent Saudis from engaging in healthy eating such as lack of willpower and lack of social support (AlQuaiz and Tayel 2009).

It is important to better understand the barriers people with diabetes have, to develop culturally tailored prevention strategies and deliver better care and management (Nagelkerk et al. 2006). However, extremely few studies have assessed cultural barriers to healthy eating within the Saudi context (Al-Saeedi 2001, Abahussain and El-Zubier 2005, AlQuaiz and Tayel 2009, Sabra et al. 2010). Hence, it is difficult to identify culturally specific barriers to healthy eating among diabetics in Saudi Arabia. The aim of this study was to apply qualitative and quantitative methods to identify cultural specific barriers among Saudi adults with and without T2DM.

Summary

In this section the introduction and rational of Chapter 11 were presented. In the next section (Chapter 11 – section 1), the pilot study of the questionnaires used to assess cultural barriers to healthy eating in Saudi adults will be presented.

Section 1 The pilot study of the cultural barriers to healthy eating questionnaire

11.1.1. Methods

A) Rational for the pilot study and questionnaire development

A thorough electronic search was conducted (MEDLINE, CINAHL) and authors were contacted was conducted to identify previously developed tools that have assessed barriers to and knowledge about healthy eating in Saudi Arabia. Two studies were identified (AlQuaiz and Tayel 2009, Sabra et al. 2010) and the reference list of the two studies were scanned for further studies. However, no further studies were identified. The authors of the two studies were contacted for the original version of the questionnaires.

In brief, the first study (AlQuaiz and Tayel 2009) was a cross-sectional study that included 450 Saudi adults. The questionnaire included 15 close-ended questions to assess barriers to a healthy diet. There were five domains and three questions covered each domain; lack of willpower, lack of knowledge, lack of time, lack of resources status and lack of social support. The questionnaire was pre-tested in 30 participants.

The second study (Sabra et al. 2010) was a cross-sectional study that included 1030 Saudi adults. The questionnaire included 7 dietary misconceptions (close-ended questions). A “yes” answer was considered a misconception. The questionnaire was piloted in a sample of PHCC attendees.

Following review of these two existing questionnaires it was apparent that not all aspects relating to food knowledge and barriers to healthy eating in the Saudi context had been explored. The content of the two questionnaires were therefore modified in design and content to produce one larger questionnaire incorporating aspects of the existing questionnaires and new items. The modification was informed by text books (Bowling 1997) and an extensive literature search (Madani et al. 1998, Rasheed 1998, Bani and Hashim 1999, Assiri 2003, Abahussain and El-Zubier 2005, Sabra et al. 2010, Sharif et al. 2010, Mohieldein et al. Vol 3, No 2 (2011)).

The modification aimed to explore areas that were not studied extensively in Saudi Arabia (Al-Gelban 2008, AL-Majwal et al. 2009, AlQuaiz and Tayel 2009, Sabra et al. 2010), such as healthy eating, approaching dieticians, and food knowledge. Two dieticians, and an expert in qualitative approaches (Griffiths, F.) reviewed the final version of the questionnaire (available in Appendix 13).

B) Questionnaire structure

The questionnaire (available in Appendix 13) consisted of three sections: section one included three open-ended questions. Section two (cultural barriers to healthy eating) was a pre-developed questionnaire (AlQuaiz and Tayel 2009), however, it was slightly amended to address people without diabetes and people with diabetes separately. Section three (dietary misconceptions in T2DM) included thirteen close-ended questions, seven of them were obtained from a pre-developed questionnaire (Sabra et al. 2010) while the remaining six were informed by the literature search and consultations with two Saudi dieticians.

C) Study setting

The pilot study of the cultural barrier to healthy eating questionnaire was conducted in two primary health care centres (PHCC's) in Riyadh, Saudi Arabia (Table 11.1). The PHCC's participated in the BSR survey in 2009. The choice of the two PHCC's was based on research nurse's availability, pilot study time frame, and transportation.

Table 11.11. Participating PHCC's in the pilot study

PHCC	Location	<i>n</i>
Al Fawaz	West-eastern province	15
Iskan AlMaathar	Central province	15

D) Selection of participants

PHCC's attendees were approached by the nurse working at each centre and asked if they were willing to participate in the pilot study. The reason for the study was explained to each participant, and they were offered a free nutritional consultation after the interview. At this stage, 30 adults (≥ 18 years) females ($n = 15$) and males ($n = 15$) agreed to join the pilot study.

E) Interview structure

Participants were greeted and the reason of the interview was explained for the second time. If participants were happy to participate, a face-to-face interview was conducted in an allocated private room at the PHCC and the interviewer completed the

questionnaire. Before conducting the interview, each participant was requested to stop the interviewer at anytime if he/she felt uncomfortable, did not understand the question and if clarification was required. After each question, the participant was asked if the question was easy to understand.

At the end of the interview, each participant was asked if the questionnaire was clear, if there were any questions that he/she were not happy with, if the process of the interview was smooth, and if they had any further comments. Every effort was made to not express in voice tone, facial expression or movement any approval or disapproval of reported answers by participants. The research nurse attended the interview to observe the interviewing process and provide feedback after each interview. The research nurses reviewed the layout of the questionnaire and questions and all comments were noted. A free nutritional consultation was offered at the end of each interview.

F) Analysis plan

For the first section of the questionnaire, the initial plan was to recode 'yes' and 'no' responses and report them in percentages (%), and to use deductive content analysis for the free text data. A deductive approach sets categories a priori to fit responses in these categories (Hsieh et al. 2005, Elo et al. 2008). The choice of categories was informed by the literature, clinical experience of the primary investigator in Saudi Arabia and by consultation with the two Saudi dieticians. The pilot of the questionnaire will inform the a priori categories. Free text data will be analysed using deductive analysis (Elo and Kyngäs 2008). After categorizing the data, results will be reported in percentages (%), with analysis stratified by sex and diabetes status.

For the second section of the questionnaire which used a pre-existing questionnaire, (by Al Quaiz et al.) the initial analysis plan was to follow the author's analysis methods. In the Al Quaiz et al. study, every three statements fell under one domain and a score was given to each domain. The scoring system was used to quantify how likely a participant would respond to each statement. The scoring system was as follows: very likely was given as score of 3, somewhat likely was given a score of 2, somewhat unlikely was given a score of 1, very unlikely was given a score of 0 (AlQuaiz and Tayel 2009).

Scores of three related statements were added to identify a category of barriers. The highest possible score for each domain is 9. A score of 5/9 or higher in any category was considered as an important barrier. The questionnaire consisted of 15 questions, with 5 domains and three questions for each domain. The 5 domains were as follows: lack of willpower (q. 1-3), lack of knowledge (q. 4-6), lack of time (q. 7-9), lack of social support (q. 10-12), and lack of resources (q. 13-15) (AlQuaiz and Tayel 2009).

For the third section of the questionnaire (a modified version of Sabra et al. questionnaire) the initial analysis plan was to follow the author's analysis methods. In the Sabra et al. study a 'yes' answer was considered as a misconception and was given a score of one. For participants who answered 'no' they were scored a zero. The total were then divided into two groups; low levels of misconception and high levels of misconception (Sabra et al. 2010).

Since the plan was to quantify the data (categorize the responses) for section 1, SPSS Statistics V.21 was a suitable program for analysis. Sex and diabetes stratification was set a priori because of the social and biological differences between females and males (Bird and Rieker 1999).

11.1.2. Lessons learnt from the pilot study

A) Study setting

The PHCC's provided a private room to conduct the interview, and the overall setting of the centre (e.g. availability of rooms, seating, interview privacy, stadiometer) seemed appropriate for data collection.

B) Sample selection

It was clear that females were less likely to visit PHCC's because of transportation issues and family obligations. The same participants who completed the FFQ (chapter 8) would be requested to complete the questionnaire of this study following their FFQ interview.

C) Interview structure

Participants felt at ease during the interview, and asking them if they would like to add anything else seemed to add to their response/answers. None of the participants complained about the nature of the questions nor felt uncomfortable during the interview. However, after completing the interviews and consulting the research nurses, it seemed that the format of the questionnaire and some questions required modification. These are outlined below.

D) Questionnaire format

The format of the questionnaire was changed to include a separate page dedicated to include additional participant's information that included weight, height, date, study serial number, and telephone number. The font size was increased for clarity, and line spacing was added to allow additional space while completing the questionnaire. Headings were added before each section of the questionnaire to orient the interviewer and participants.

E) Questions content and format

In the first section (open-ended questions), question number one "*Does healthy eating matter to you?*" seemed unclear to some participants, as some asked, "*What do you mean by healthy eating?*" or "*What is healthy eating?*". Therefore, an additional question was added "*How would you define a healthy diet?*"

Question number three "*Do you know the foods that people avoid to prevent diabetes?*" seemed an unclear question. For instance, most participants reported food groups (e.g. carbohydrates, fats). When reporting "carbohydrates" as an answer, some of the participants struggled to pronounce the word. While naming foods, some hesitated while answering and thought out loud by saying "*Oh no, this food is good for you*" or "*No, this food is good, is it?*" Therefore, two additional questions were added to overcome this confusion, "*Do you know the foods that people consume more to prevent diabetes?*" and "*Do you know what carbohydrates are?*"

In the second section of the questionnaire, participants were confused when given the options of: no never, no rarely, yes sometimes, or yes always. It seemed that mentioning no/yes prior to the options complicated the nature of the question. Therefore, no/yes were not verbally mentioned when asking the participant.

In the third section, Question number ten '*Excess weight does not affect people with diabetes*' was not clearly understood by participants and was changed to '*Abdominal obesity is not associated with diabetes*'.

F) Incentives

Participants were very interested in the free nutritional consultation after the interview, and research nurses encouraged that. However, the majority of participants requested a blood glucose test, which was taken into account as an additional incentive for data collection in the main study.

G) Analysis

For the first section of the questionnaire (free text data) deductive analysis was not suitable for all questions because of the large number of categories generated. In addition, loss of data occurred when categorizing the responses. For the third section of the questionnaire (modified version of Sabra et al. questionnaire) the response "I don't know" was reported, and that was not accounted for in Sabra *et al.* analysis method (Sabra et al. 2010). Therefore, the analysis plan was modified and results would be reported as frequencies (%) for three categories: misconception, no misconception, and

no answer. The analysis plan was modified to better suit the nature of the data and that will be explained in detail in the analysis of the second section of this chapter.

H) Back translation

The interviews were conducted in the Arabic language, and the primary investigator carried out back translation to the English language. There were no issues with back translation; however, support from a bilingual researcher was requested to approve the translation.

Summary

In this section the methods of the questionnaire development and pilot study were presented. The lessons learnt from the pilot study to incorporate into the main study were also presented. In the next section, the methods, results and discussion of the cultural barriers to healthy eating in Saudi adults study will be presented.

Section 2 Cultural barriers to healthy eating and T2DM

Introduction

In this section, the cultural barriers to healthy eating in diabetics and non-diabetics are presented for a subsample ($n = 108$) of the original cohort ($n = 2631$) of the Biomarkers Screening in Riyadh survey (BSR), with analyses stratified by sex and diabetes status. In this section the methods of data collection, results and discussion are presented.

11.2.1. Methods

A) Study setting

The current study was conducted in six primary health care centres (PHCC's) in Riyadh, Saudi Arabia (Table 11.2). The PHCC's participated in the BSR survey in 2009. The choice of the six PHCC's was based on research nurse's availability, research costs, data collection time frame, and transportation.

Table 11.12. Participating PHCC's in the current study

PHCC	Location	<i>n</i>
Al Fawaz	West-eastern province	32
Al Marwa	West-eastern province	92
Ghubairah	Central	19
Iskan AlMaathar	Central	24
Al Badiah	Southern province	97
Al Naseem Al Shargi	Eastern province	81

B) Sampling plan

The sample was a convenient sample, the same participants that completed the FFQ were chosen for this study. In qualitative studies, sampling methods are not based on statistical power or probabilities (Curtis et al. 2000). Marshall suggested that a sampling plan in qualitative studies should be practical and realistic (Marshall 1996). Miles and Huberman (1994) suggested that sampling methods could be evaluated through six domains (Miles et al. 1994):

1. **The sampling plan should be relevant to the research focus:** intrinsic selection, the cases (T2DM) are pre-specified, was followed because of the focus/aims of this project (Curtis et al. 2000). An internal sample (sub-sample of the original cohort of this project) that included participants with (T2DM) and without the condition to explore the difference between groups.
2. **The sample should be likely to generate information about the studied factors:** the sample included participants with and without T2DM.
3. **The sample should enhance analytic generalizability of the findings:** some aspects were met, the sample was a convenient sample that included females and males, participants with and without diabetes and from different areas in Riyadh (central, eastern, southern and west-eastern areas). Although a random sample enhances generalizability of the findings to the population, Marshall argues that this is not the most effective method in qualitative studies because of practical and theoretical factors. Believes that understanding peoples perceptions, beliefs and behaviours are more important than generalizability (Marshall 1996).
4. **The sampling method should be ethical:** written consent was obtained from all participants, Ethical approval was granted from both the Ethics Committee of

the College of Medicine Research Centre, King Saud University, Riyadh, KSA (available in Appendix 8). UK ethical approval was obtained from the Biomedical Research Ethics Committee of the University of Warwick (available in Appendix 9).

- 5. The sample should produce believable descriptions (in a sense related to real life):** participants provided “honest” answers with no pressure, judgement, approval or disapproval from the interviewer. All participants were interviewed alone in a designated room at their local PHHC to ensure privacy during the interview.
- 6. Feasibility of the sampling plan:** participants that joined the FFQ calibration study completed the questionnaire of this study. Research costs and time restraints were accounted for during the sampling plan.

C) Selection of potential participants

In the current study, the same participants that were invited to join the FFQ calibration (Chapter 9 – section 1: sample selection) were invited to join this study. The sample of this study was an internal sub-sample of the original BSR (2009) cohort. Research nurses were contacted prior data collection to discuss the sampling plan, however, missing/changed contact details was the main challenge. Therefore, all of the 345 participants in the six PHCC’s were selected for the current study (previously clarified in Chapter 9 – section 1: sample selection). The serial numbers were sent to research nurses prior data collection to identify potential participants. Although the sample was a convenience sample, the sampling plan met Miles and Huberman (1994) criteria (Miles and Huberman 1994).

D) Invitation of potential participants

Six research nurses working at the PHCC's (Table 11.1.) who delivered care to participants of the original BSR survey (2009) invited participants through telephone calls. Telephone calls are the communication method used between PHCC's and registered citizens at the centres. The serial numbers of the 345 participants was given to the nurses to invite participants to their local PHCC. Nurses reviewed the serial numbers of potential participants and identified available contact details. Nurses explained the objectives of the study over the phone, and participants who were happy to join were invited to their local PHCC to provide written consent and be interviewed.

E) Incentives

Participants who agreed to join the study were offered a free blood glucose check using a glucometer. Beverages and snacks were also offered to participants and to whoever accompanied them at the time of the visit. Participants who completed the study were offered a free nutrition consultation for themselves and family members. They were also permitted to communicate with the primary investigator for any nutrition related queries.

F) Mode of administration

Participants who agreed to join the study over the phone arrived to their local PHCC. At the PHCC, the primary investigator explained the aims of the study for a second time to ensure that participants were fully aware of the study objectives and to answer any

questions. Participants who agreed to join the study provided written consent and were interviewed.

G) Questionnaire structure

The pilot study (the first section of this chapter) helped in modifying the cultural barriers to healthy eating questionnaire. The revised version of the questionnaire is available in Appendix 14. The questionnaire development and modification were discussed in the first section of this chapter (the pilot study).

The cultural barriers to healthy eating questionnaire consisted of three sections:

1. Section one (developed for this current study): included six open-ended questions with free text response.
2. Section two – barriers to healthy eating: included the pre-developed questionnaire by Al Quaiz et al. (AlQuaiz and Tayel 2009). At this stage, participants were asked if they had diabetes and if so were asked the questions specifically for diabetics, otherwise they were asked the questions for non-diabetics.
3. Section three – dietary misconceptions in T2DM: included the modified version of the pre-developed questionnaire by Sabra et al. (Sabra et al. 2010).

H) Interview structure

After completing the FFQ interview, the cultural barriers to healthy eating interview started. Each section of the cultural barriers questionnaire was explained prior

interviewing and participants were asked to talk freely. Face to face interviews were carried out at a designated room at the PHCC. The primary investigator interviewed participants and completed the questionnaire. The interviewer did not express in voice tone, facial expression or movement any approval or disapproval to reported answers. After each open-ended question, participants were asked if they would like to add any further comments/answers. After completing the first section of the questionnaire, participants were asked for a second time if they would like to add anything else. The interview lasted for around 25 minutes, however, that varied from one participant to another.

11.2.2. Data analysis

A) Data preparation and data entry

The questionnaire included three sections: open ended questions, barriers to healthy eating and dietary misconceptions. Primarily, all data were in paper form and written in the Arabic language. The primary investigator carried out back translation which was reviewed by a second bilingual (Arabic – English) researcher. There were two types of data: qualitative data and quantitative data. The qualitative data (the first section of the questionnaire) include the free text responses to the open ended questions of the first section of the questionnaire. Free text data were entered in a word document and then exported to N Vivo for data management. Quantitative data (the second and third sections of the questionnaire) included barriers scores and misconceptions. Quantitative data were entered in SPSS Statistics V.21.

B) Qualitative data (the first section of the questionnaire – free text data)

Data coding of the first section of the questionnaire

Data coding and management was carried out in Nvivo software. Coding is a method of data management that helps in organizing the data. Coding is a process of labeling or categorizing the data, each code has a name that refers to a passage/passages in the raw data (free text – participant responses). A code can be renamed to a parent code when it has a smaller (child) code that falls under the main/parent code. A sub-code is a smaller code of the child code (Gibbs 2008). A coding hierarchy is shown in figure 11.1. During the process of data coding, the serial number of each respondent was added next to each coded text, and this was carried out before sex and diabetes stratification to reduce coding bias.

The pilot study (the first section of this chapter) informed the coding approach of the current study. Two coding methods were followed, deductive (the codes are generated a priori) and inductive (the codes generated from the data) methods (Thomas 2006). Deductive coding or “concept-driven coding” is when the categories and labels are generated before examining the data (Elo and Kyngäs 2008, Gibbs 2008). However, it is possible to amend the codes as new ideas generate during the analysis of the data (Gibbs 2008). In this study, the pre-developed codes were generated from the literature, the pilot study and reviewed by the research team of this project. Inductive coding is the opposite of deductive coding where the codes are driven by the data. It is an open coding method where the researcher relatively starts coding the data with an “open mind” before the process of data coding (Gibbs 2008).

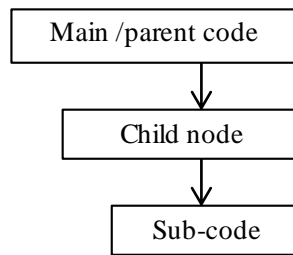


Figure 11.1. Coding frame hierarchy

Coding strategy for questions 1-3 (the first section of the questionnaire)

<p>1. How would you describe a “healthy diet”? (free text response)</p> <p>.....</p> <p>2. Does “healthy eating” matter to you?</p> <p>a. Yes</p> <p>b. No</p> <p>If yes why? (free text response)</p> <p>If not, why not? (free text response)</p> <p>.....</p> <p>3. Have you ever seen a dietician?</p> <p>a. Yes</p> <p>b. No</p> <p>If yes why? (free text response)</p> <p>If not, why not? (free text response)</p> <p>.....</p>

Box 1. Questions 1-3 from the first section of the questionnaire

The pilot study showed that inductive coding was the best approach to code questions 1-3. Codes were generated from the text itself (participant responses) using a systematic approach. Notes were taken while coding, “parent” codes were generated with “child” nodes and “sub nodes” as appropriate. Two reviewers carried out the revision of the codes and the coded text after each question and amendments were made as appropriate. Repetitive codes were combined. Two reviewers reviewed the final coding frame, an example of a coding frame is available in table 11.3.

Table 11.13. Coding frame for question 1: *How would you describe a healthy diet?*

Code	Definition	Hierarchy
Physical activity	Any type of activity (i.e. exercise, walking).	Main code
Lack of knowledge	Not having the knowledge to provide an answer (i.e. I don't know, I have no idea).	Main code
Issues with diet	Mentioning issues/problems (i.e. family issues, lack of time).	Main code
Health	Factors associated with human health (i.e. maintain your health, good for health).	Main/parent code
Harm	Factors associated with harming your health/body (i.e. sweets will harm me, eating extra is a burden).	Child code of health
Disease prevention	Preventing diseases and chronic conditions (i.e. diabetes, not get a disease).	Child code of health
Disease management	Managing chronic conditions (i.e. diabetes management, hypertension management).	Child code of health
Body weight	Talked about body weight management and reduction (i.e. low body weight, prevents weight gain).	Main code
Balanced diet	Talked about aspects of a balanced diet in general (i.e. food groups, variety).	Parent code
Quantity	Talked about portions and amounts (i.e. three meals, calories).	Child code of balanced diet
Foods to reduce	Included food items that should be reduced (i.e. fat, sugar).	Sub-code of quantity
Foods to include	Mentioned food items that should be included in a healthy diet (i.e. goats milk, leafy vegetables).	Child code of balanced diet
Foods to avoid	Mentioned food items that should be eliminated from the diet (i.e. saturated fat, sugary juices).	Child code of balanced diet
Cooking style	Describes some cooking styles that should be followed (i.e. boiled, grilled).	Child code of balanced diet

Note: The examples given for each code are from the raw data (participants responses)

Coding strategy for questions 3-6 (the first section of the questionnaire)

<p>4. Do you know which foods people should eat less of to reduce the risk of getting diabetes?</p> <p>a. Yes b. No</p> <p>If yes, could you please list? (free text response)</p> <p>5. Do you know which foods people should increase to reduce the risk of getting diabetes?</p> <p>a. Yes b. No</p> <p>If yes, could you please list? (free text response)</p> <p>6. Do you know what Carbohydrates are?</p> <p>a. Yes b. No</p> <p>If yes, could you please give some examples? (free text response)</p>

Box 2. Questions 4-6 from the first section of the questionnaire

The pilot study showed that a combined approach of both deductive and inductive coding was the most appropriate to code data from questions 3-6. Deductive codes, set a priori, were based on the healthy food palm for the Kingdom of Saudi Arabia (Al-Dkheel 2012). The a priori codes included 7 groups, water, cereals and breads, fruits, vegetables, meat and legumes, milk and dairy, oils and sugar (Al-Dkheel 2012). However, an inductive approach was applied for responses that did not fit within the 7 categories. Inductive codes were generated from the text itself (participants responses). All codes and the text coded were reviewed prior analysis. Two researchers reviewed the final coding frame, an example of a coding frame is available in table 11.4.

Table 11.14. Coding frame for question 4: Do you know which foods people should eat less to reduce the risk of getting diabetes?

Code	Definition	Type
Cereals and bread	Food items that fell under cereals and bread food group (i.e. white bread, rice).	Deductive
Fruits	Food items that fell under fruits food group (i.e. dates, banana).	Deductive
Oils and sugar	Food items that fell under this oils and sugar food group (i.e. fizzy drinks, chocolate).	Deductive
Meat and legumes	Food items that fell under meat and legumes group (i.e. eggs, red meat).	Deductive
Diet related	Related to different aspects of the diet and did not fall under the a priori categories (i.e. coffee, reduce salt).	Inductive (parent code)
Physical activity	Any type of activity (i.e. walk a lot, exercise).	Child code of diet related
Dietary patterns	Responses included/referred to clear dietary patterns (i.e. fast food, traditional food).	Child code of diet related
Dietary behaviours	Responses included behaviours or eating behaviours (i.e. you eat and sit, decrease your food).	Child code of diet related

Note: The examples given for each code are from the raw data (participants responses)

Analytical theories

One of the important factors in conducting qualitative analysis is that the researcher has to be extremely familiar with the data to provide insightful analysis (Braun et al. 2006). In this current study that was carried out, the researcher conducted the interviews, collected the data, carried out back-translation, entered the data, coded the data and analysed the data. Qualitative data analysis has different approaches; one of the most common methods applied is the grounded theory (Stern et al. 1985, Eysenbach et al. 2002, Phillips et al. 2007). The grounded theory is an approach that generates themes/ideas/concepts from the data obtained, it is a method of understanding the data from the data. The discovered themes/ideas/concepts are supported “grounded” by the raw data. The grounded theory has different aspects that help in the analysis stage such as open coding and constant comparison (Strauss et al. 1994). Open coding is the

process of generating concepts and ideas from the data, and the use of analytic codes rather than descriptive codes is recommended. The researcher should constantly ask questions (i.e. why? who?) while reading the data to help in developing ideas and move towards a deeper analytic stage.

Constant comparison uses contrasts to help in understanding the ideas and concepts behind the text. There are several techniques used to help in applying constant comparison, such as the flip-flop technique and waving the red flag. The flip-flop technique compares extremes, for example comparing the healthy to the diseased or females to males to discover the different issues that they report. Waving the red flag is being sensitive to signal words like “always”, “never” and looking deeper in what the respondent meant by that (Gibbs 2008).

Thematic analysis, includes some aspects of the grounded theory, and is a qualitative analytic method that aims to identify and report themes/patterns within the data. Themes are generated by bringing together codes, components of text, or fragments of the data to capture an important feature of the data. Emerging themes generate from combining fragments of the data “codes” to generate a wider picture/story of the data. Sub-themes, which are smaller fragments of the emerging themes, provide a comprehensive observation and generate emerging patterns in the data (Aronson 1994, Braun and Clarke 2006, Guest et al. 2011).

For the analysis of this study thematic analysis was applied. After coding the data, the codes and text were printed for the purpose of analysis. The coded data (raw data) was read several times and notes/text/ideas were documented under each code. Similar codes were combined together in one sheet of paper (OSOP) with constant referral to

the coded text (raw data). The grouped codes/data were constantly read and re-read to identify associations, patterns, themes and subthemes.

Qualitative data analysis

The analysis of the free text data was an iterative process that had different stages. The process of analysis is shown in figure 11.2. Visual materials are available in Appendix 15 on the process of qualitative data analysis (examples).

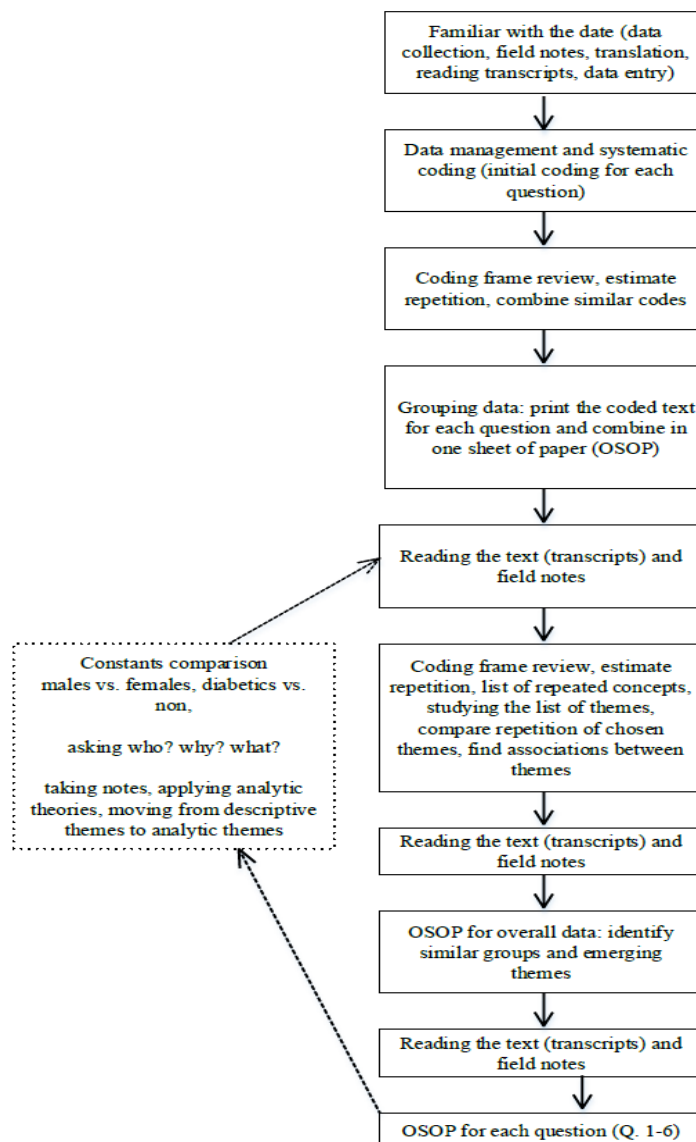


Figure 11.2. The process of qualitative data analysis

C) Quantitative data analysis

The second and third section of the questionnaire included quantitative data (barriers to healthy eating and dietary misconceptions in T2DM). Data were manually entered in SPSS Statistics V.21 with the serial number of each participant.

Statement	0– No never	1-No sometimes	2-Yes sometimes	3-Yes always
1. I lack the motivation to follow a healthy diet				
2. I cannot resist traditional food				
3. I do not want to follow a healthy diet because I previously failed to do so				
4. I don't want to change my eating habits because I do not have any health problems				
5. I do not believe that there is a relationship between unhealthy diet and diabetes				
6. I do not need to eat fruits and vegetables because I take vitamin supplements				
7. I cannot follow a healthy diet because I stay away from home for most of the day				
8. I was not exposed to educational programs that can educate me about healthy eating				
9. I do not have enough time to prepare healthy meals				
10. I do not follow a healthy diet because I will feel deprived when I look at what others are eating				
11. My family do not help/support me to follow a healthy diet				
12. Social gatherings/commitments stops me from following a healthy diet				
13. Fast food media influence my eating habits				
14. I like fast food because it is easy to get				
15. I do not buy healthy food because it is expensive and has a short shelf life				

Box 3. The second section of the questionnaire

For the second section of questionnaire (Barriers to healthy eating questionnaire by Al Quaiz *et al.* (AlQuaiz and Tayel 2009)): every three statements fell under one domain and a score was given to each domain. A scoring system was applied as follows: Very likely was given a score of 3, somewhat likely was given a score of 2, somewhat

unlikely was given a score of 1, very unlikely was given a score of 0 (AlQuaiz and Tayel 2009). Scores of three related statements were added to identify a category of barriers. The highest possible score of each domain is 9. A score of 5/9 or higher in any category will be considered as an important barrier. There were 5 domains as follows: lack of willpower (q. 1-3), lack of knowledge (q. 4-6), lack of time (q. 7-9), lack of social support (q. 10-12), and lack of resources (q. 13-15) (AlQuaiz and Tayel 2009). Results were reported for the overall sample, sex and diabetes stratified groups.

Do you agree with the following statements?	Yes	No
<i>1. People with diabetes that are on medications can eat any type of food</i>		
<i>2. Dates are very important for the health of people with diabetes</i>		
<i>3. Honey is good for people with diabetes</i>		
<i>4. All carbohydrates should be removed from a diabetic diet</i>		
<i>5. Bitter food will reduce high blood glucose</i>		
<i>6. Toasted bread contains less sugar than normal bread</i>		
<i>7. Regular intake of snacks between meals is essential for adults with type 2 diabetes</i>		
<i>8. Beans, lentils and corn do not contain carbohydrates</i>		
<i>9. Fresh fruit juice is better than whole fruit for people with diabetes</i>		
<i>10. Abdominal obesity is not associated with diabetes</i>		
<i>11. Vegetables will not help in regulating sugar levels in people with diabetes</i>		
<i>12. There is only one diet people with diabetes should follow</i>		
<i>13. Portion size is not important for people with diabetes</i>		

Box 4. Third section of the questionnaire

For the third section of the questionnaire (Dietary misconceptions questionnaire by Sabra *et al.* (Sabra *et al.* 2010), modified and piloted in this current study): misconception, no misconception, and no answer were coded and reported as frequencies (%) for the overall sample, sex and diabetes stratified groups.

11.2.3. Results

A) Response rate

The total number of potential participants registered at the six PHCC's was 345 participants. Only 185 participants had available contact details, while the remaining 160 had missing/unavailable contact details. Nurses contacted the 185 individuals, where 77 individuals were either not available (e.g. travelling), could not be interviewed (e.g. primary investigator could not access the male section at the PHCC, participants could not provide written consent), did not show up, refused to join or moved to a different area. A total of 108 participants agreed to join the study and provided written consent. The response rate of the current study was therefore 58.4%, however, there were no significant differences for the general characteristics between respondents ($n = 108$) and non-respondents ($n = 77$) (Table 11.5.)

Table 11.15. Descriptive* characteristics of the respondents and non respondents

Variable	Respondents	Non respondents	<i>p</i>
<i>n</i>	108	77	
Age (yrs)	43.17±13.58	43.23±16.71	0.976
Sex (%)			
Female	23.1% (25)	19.5% (15)	0.550
Male	76.9% (83)	80.5% (62)	
Weight (kg)	82.46±16.44	77.72±15.52	0.051
BMI (kg/m ²)	30.05±5.79	28.50±5.82	0.078
WC (cm)	97.52±16.36	95.21±15.23	0.345
SAD (cm)	24.52±9.18	22.92±8.31	0.240
Systolic (mmHg)	121.73±12.96	120.27±14.51	0.513
Diastolic (mmHg)	78.80±7.12	76.89±8.49	0.134
FPG (mmol/L)	6.36±1.40	6.70±1.60	0.387
Cholesterol (mmol/L)	5.00±0.86	4.89±1.20	0.484

TG (mmol/L)	2.71±1.41	2.48±1.35	0.067
LDL-cholesterol (mmol/L)	3.63±0.88	3.63±0.91	0.989
HDL-cholesterol (mmol/L)	0.51±0.18	0.57±0.21	0.073
Free from HTN	83.3% (75)	80.3% (53)	0.626
HTN	16.7% (15)	19.7% (13)	
NDM	50.9% (55)	62.3% (48)	0.613
PDM	10.2% (11)	7.8% (6)	
T2DM	38.9% (42)	29.9% (23)	
Family history of diabetes			
No family history	11.8% (9)	15.0% (9)	0.177
1 st degree family history	55.3% (42)	45.0% (27)	
2 nd degree family history	9.2% (7)	21.7% (13)	
1 st & 2 nd degree family history	23.7% (18)	18.3% (11)	

*Percentages (n) or mean values ± SD; **BMI** indicates body mass index; **WC** indicates waist circumference; **SAD** indicates sagittal abdominal diameter in cm; **FPG** indicates fasting plasma glucose; **TG** indicated triglycerides; **HTN** indicates self-reported hypertension, or use of HTN drugs or systolic ≥ 140 mmHg or diastolic ≥ 90 mmHg; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **PDM**: pre-diabetes (self-reported pre-diabetes or FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **T2DM**: type 2 diabetes mellitus (self-reported T2DM or FPG ≥ 7.0 mmol/L; ≥ 126 mg/dL); **Family history of diabetes**: 1st degree includes father, mother, siblings or children. 2nd degree includes uncle, aunt, grandparents or grandchildren.

B) Section one: Qualitative findings (free text data)

The analysis was an iterative process as shown in figure 11.2. Referral to the text, codes, and coded text was carried out along with application of analytic theories. A brief overview of themes for the overall data is presented in table 11.6. Detailed thematic analysis for each question was carried out and they are as follows:

Question 1. How would you describe a “healthy diet”?

The definition of healthy eating and reported practices varied among participants. In general, healthy diet incorporated five core themes:

Theme one: Health benefits

Theme two: Being active

Theme three: Lack of knowledge

Theme four: Cultural issues

Theme five: Diet characteristics

Each of the core themes incorporated several subthemes and they are as follows:

Theme one. Health benefits

The majority associated healthy eating with general health. Healthy eating was perceived as ‘good’, ‘harm-free’ and ‘beneficial’. Participants with no diabetes defined healthy as being able to carry out daily activities, while participants with diabetes defined healthy as being free from disease. The core theme ‘health benefits’ was generated from two subthemes and they are as follows:

1. ‘Prevention from harm’ (sub-theme)

Overall, participants believed that a healthy diet would prevent ‘harm’ in general and disease specifically ‘*A diet is to protect yourself from stuff... so you don’t harm yourself. You avoid what is harmful for your body or reduce them so you will not get diseases, may God forbid – A40123*’. Disease prevention was flagged clearly among diabetics, especially males, in comparison to non-diabetics ‘*Prevention from diabetes and high blood pressure - A07125*’.

Table 11.16. Summary of themes and definitions for the overall data

Theme	T2DM	Both	NDM
Health benefits	<ul style="list-style-type: none"> - Free from disease. - Males: Precious health. 	<ul style="list-style-type: none"> - Diabetes was the main disease reported. - Better health associated with healthy eating, 'for sure', 'of course' healthy eating matters. - Females: Important for children/concerned about children. 	<ul style="list-style-type: none"> - Carry out daily activities. - Strong, fit, better mental well-being. - Personal effort to improve lifestyle with sense of achievement.
a) Prevention from harm	- Disease prevention		- Prevention from harm in general
b) Health maintenance	- Males: Glucose levels control, GP referral to a dietician for glucose control.		<ul style="list-style-type: none"> - Males: Fit and healthy - Healthy body in general, getting older.
c) Body weight	- Females: Weight gain, GP referral to a dietician for weight reduction.		- Reduce body weight.
Lack of knowledge		- Cannot define/struggle.	
Cultural issues			
a) Change of culture	- Males: Change of the environment/pastimes are better.		Males: Fast food – westernization.
b) Lack of social support	- Males: Complain of lack of support in the family.	- Males: Culturally inappropriate to seek dietary modification.	- Males: Burden on the family, overeating at social commitments.
c) Reliance		- Males: Others (health care providers) should take care of them.	
d) Resistance	<ul style="list-style-type: none"> - Males: Confirmed/acknowledged the refusal to change in the Saudi culture. - Males: Lack of need/God, positive attitude. 		<ul style="list-style-type: none"> - Males: Busy life, lack of interest. - Females: Negative voice tone/ body language/don't need.
Limitation of the		- Complain/anger/ can't get the service/ don't	- Males: Lengthy process.

health care system		<p>follow up in hospitals.</p> <p>- Don't know how to get lifestyle modification service.</p>	
Diet characteristics	- Harmful food, negative about food.	<p>- Males: Skipping meals.</p> <p>- Females: Only fruits and vegetables.</p>	Males: Good/fresh food, positive about food.
Food confusion		<p>- Repetition of the same food using different names.</p> <p>- Confused about food groups.</p>	
Misconceptions	<p>- Males: Dry/Bitter food is good.</p> <p>- Males: Oranges/bananas are bad.</p>		- Males: Dry food is good.

T2DM indicates participants with type 2 diabetes; **Both** indicates females and males with and without diabetes unless sex was specified; **NDM** indicates participants with no diabetes.

2. *'Helps in health maintenance' (sub-theme)*

Participants thought that a healthy diet would help maintain their current health. The idea that healthy eating would keep you 'fit' and 'healthy' and that healthy eating does not worsen your condition. This was mentioned clearly among males with no diabetes in comparison to others *'It helps the person to be in a good state in every aspect such as drinking, waking up, sleeping and everything. It helps him to be healthy – A40061'*.

Theme two. Being active

Physical activity was identified as a factor in the definition of healthy eating, this factor that was mainly flagged by males with diabetes *'Performing the suitable exercise - A40114'*. Exercise was mainly described as walking *'walk, walk a lot – A44042'*.

Theme three. Lack of knowledge

Lack of knowledge was clear among participants, in both males and females. Lack of knowledge was more common among males in comparison to females. Males with and without diabetes were not able to define or describe a healthy diet *'I don't know, I don't know anything – A07121'*, or struggled when asked *'Oh god, what do I tell you...I don't know – A010231'*.

Theme four. Cultural issues

Participants talked about cultural characteristics, change in culture and some personal characteristics of Saudi individuals were identified. The core theme emerged from four subthemes.

1. *'Change of culture' (sub-theme)*

Males with diabetes acknowledged the change of the Saudi culture over time and how that change influenced their eating habits *'In the old days it was meat, camels milk and rice. Nowadays you avoid fat, you know, according to nowadays changes and needs - A44045'*. They believed that the 'old times' and 'old lifestyle' were better *'The Bedouin lifestyle, such as rice, meat and date –A44076'*, and that the spread of fast food restaurants is harmful *'Avoid eating at restaurants and shopping malls, it has bad stuff – A44015'*.

2. *'Lack of family support' (sub-theme)*

Lack of social support was perceived as a barrier to follow a healthy diet. Participants indicated that members of the family did not support the practice of healthy eating at home *'Controlling your diet is very important. Ahh but what can I say, kids are at the university, my wife is sleeping most of the time, and I am at work – A44080'*.

3. *'Reliance' (sub-theme)*

Participants thought that it is not their responsibility to personally make the effort in order to learn or know about healthy eating. They believed that it is the responsibility of

health care professionals to deliver the information. This trend was clear among males with diabetes '*Knowledgeable people will give me the information – A42026*'.

4. '*Resistance*' (sub-theme)

Resistance was observed in both body language and answers. Males with diabetes acknowledged that people refuse to change their dietary habits '*A person should have control over the food that he should avoid, but there are people that never listen - A07128*'.

Theme five. Diet characteristics

Participants mentioned dietary habits, healthy practices and foods when talking about a healthy diet. However, these factors differed across groups. Males thought that healthy diet should not involve skipping meals '*Three meals a day, they should be balanced, regular. And if you eat more it should be sugar free. Most importantly you have three meals a day - A40097*', while females thought it involved the consumption of fruits and vegetables alone '*Only fruits and vegetables, which I don't like – A33111*'.

Males with diabetes constantly referred to 'harmful' foods such as fat, sweets and rice which indicated negativity when talking about food. On the other hand, males with no diabetes were more positive when mentioning food items and referred to them as 'good' food such as bran and fresh food. None of the participants mentioned the amount of servings that should be consumed (e.g. fruits and vegetables) which indicated that portion was not very clear to them '*Regulate your eating habits, don't be hungry and don't be very full - A07097*'.

Question 2. Does “healthy eating” matter to you?

All participants believed that healthy eating matters to them and the majority associated healthy eating with health. In general, two core themes emerged from this question:

Theme one: Health benefits

Theme two: Cultural issues

Theme one. Health benefits

The majority of participants associated a healthy diet with overall better health, and they acknowledged that healthy eating is good for them. Their instant response was ‘of course’, ‘for sure’ and ‘definitely’. The definition of health differed across participants, males with diabetes perceived health as precious ‘*My health is the most valuable thing to me, you can’t compensate health – A42006*’. On the other hand, participants without diabetes defined health as being strong and fit ‘*To be fit, to be healthy, for my body and psychology – A40114*’. Additionally, they associated health with better mental wellbeing ‘*Obviously, a healthy brain is in a healthy body, we were taught that when we were kids – A44008*’.

Healthy eating mattered for personal and family reasons. Health benefits incorporated three subthemes:

1. ‘Disease prevention’ (sub-theme)

The majority of participants mentioned disease prevention, both males ‘*It has a good effect, protects the body and general health – A44034*’ and females ‘*If I follow healthy eating I will avoid two thirds of diseases – A44085*’. Prevention included the prevention

of diabetes and lipid abnormalities '*Because healthy eating prevents diseases such as diabetes and cholesterol – A44055*'.

Although both females and males mentioned disease prevention as a reason why healthy eating matters to them, females seemed to be more concerned about their body weight in terms of weight reduction '*To lose weight because my legs hurt – A44023*'.

2. 'Health maintenance' (sub-theme)

Maintaining health was perceived differently across groups, participants with diabetes focused on maintaining blood glucose levels '*So your diabetes, blood sugar won't get higher and not develop additional diseases. I have to maintain my health. I avoid anything that harms me or affects me badly – A07042*'. Additionally, healthy eating mattered to them because of their current health condition '*I am a man with diabetes and blood pressure, so I avoid the things that harm me – A42078*'.

On the other hand, health maintenance among participants with no diabetes was maintaining a healthy body in general '*Maintain vitamin levels in the body, it provides the human body with what it needs, for health – A01025*'. Additionally, they believed that if they did not follow healthy eating their health will deteriorate '*It will give me a break from going to the health care centres, if we don't our health will get worse – A44085*', and aging was a possible factor for maintaining good health '*For humans health and body, we are getting older – A44056*'.

3. 'Childs health' (sub-theme)

Healthy eating mattered to females because they were concerned about their children in terms of being there for them *'For health and so you can be strong enough to raise your kids and live – A44069'*, teaching their children about healthy eating *'Lose weight, protect myself from diseases and diabetes. I teach my children about it – A44053'* and providing better health to the children *'It gives my children immunity – A44014'*.

Theme two. Cultural issues

Males reported some Saudi cultural factors which influenced their dietary behavior; however, these factors differed among participants with and without diabetes. Cultural issues incorporated three subthemes:

1. 'Change of culture – westernization' (sub-theme)

Males with diabetes associated the change in culture and environment with disease development, as they had developed diseases that did not exist in the past *'Back in the time there were diseases, in our previous generations, but now we have diseases that weren't there in the past. We have a lot of diseases that people never got back in the days – A07045'*. While males with no diabetes blamed the westernized Saudi culture *'Because I can see that the situation is not good at all, especially with the wide spread of fast food restaurants and the children got used to them. We are suffering from anemia in girls – A44073'*.

2. 'Social pressure' (sub-theme)

Males without diabetes reported that Saudi social pressure affects their dietary behaviors. One of the factors mentioned was the pressure of taking care of themselves for future generations *'For my body's health. I am at an older age and I don't want to go through the same mistakes that my father did. I don't want to be in a bad situation and have a heavy weight and become a problem or a burden to the people around me. This issue always concerns me and I have my eyes on it. I like to have a reasonable body weight because its effect will reflect on my heart – A44134'*. Others complained from the pressure to over-eat at social occasions *'Because I have a big belly now, and I have digestion problems. I feel very bad on the following day of a social occasion. I am not into rice as I was before. Oh by the way, my food is much less than before – A44117'*.

3. 'Resistance to change' (sub-theme)

Males with diabetes acknowledged the Saudi attitude towards following a healthy diet *'Because it is healthy but we don't apply it properly – A07016'* or maintaining a healthy lifestyle *'No one maintains his health - A42007'*. However, males without diabetes blamed their busy life for not following a healthy diet *'I know how important it is, but because of work. I know how reckless I am when comes to diet – A42066'*.

Question three (a). Have you ever seen a dietician? yes answers

Less than half of the participants ($n = 40$) had consulted or seen a dietician or health care professional for lifestyle modification previously. This question incorporated one core theme:

Theme one. Health improvement

Of those participants who had previously seen a dietician/health educator, lifestyle modification or control and improvement of current health conditions were common reasons. Weight reduction was an important factor among females ‘*Yes I did, because of weight gain – A010205*’ whilst diabetes control was an important factor among males with diabetes. Overall, ‘physicians referral’ or ‘by chance’ were the main reported factors for seeking out health education. The ‘health improvement’ theme incorporated two subthemes, and they are as following:

1. ‘Improving health – through the health care system’ (sub-theme)

The majority of participants were referred to a dietician/health educator through their primary health care physician rather than self-referral. Participants with diabetes reported physician referral, males with diabetes were referred to control their diabetes ‘*The doctor referred me because of my diabetes – A40128*’ whilst females with diabetes were referred because of weight gain ‘*Doctor referred me to lose weight – A44004*’. In general, males were exposed to some lifestyle education at their local primary health care centre by chance ‘*One of them visited our centre – A44005*’.

2. ‘Lifestyle modification –personal effort’ (sub-theme)

Personal effort to consult a dietician/health educator emerged among participants with no diabetes, in both males ‘*I personally went to one for weight reduction – A40061*’ and females ‘*I personally asked the hospital to refer me to one because I wanted to lose weight – A010026*’. Some sense of achievement/being proud was observed when they

mentioned personal effort. In general, males seemed to engage more in lifestyle modification resources (i.e. gym, health clubs) in comparison to females ‘*Yes, at the gym. I go to the gym and they run nutritional sessions every Tuesday – A44048*’, ‘*Yes, at the health club – A44078*’. Only one female mentioned a lifestyle modification resource ‘*I have a membership in a health club and they taught us to avoid fats and traditional food that is full of ghee and fat – A44085*’. Only two participants with diabetes reported that they made the effort to seek dietary advice ‘*I personally wanted to see one for diabetes – A42005*’, ‘*Yes, at the gym, I met with a nutritional trainer – A44094*’.

Question three (b). Have you ever seen a dietitian? no answers

Most participants in this sample have not been exposed to a dietitian/health educator consultation (68/108). The reasons why not incorporated two core themes and they are as following:

Theme one: Limitations in health services

Theme two: Personal and cultural issues

Theme one. Limitations in health services

In general, participants (with and without diabetes) complained about the difficulties they face in getting the service (dietary/health education). They seemed to be angry at the health care system when responding to this question. Some associated this service with having to follow up in hospitals ‘*I did not have the chance to follow up in hospitals – A40158*’, ‘*I don’t follow up in hospitals – A44080*’. Males (with and without diabetes) complained about the lack of services at their local primary health care centre ‘*We don’t have any in our centre – A07121*’, ‘*They are not available in most centres – A44117*’.

Males with no diabetes complained about the lengthy process required to see a dietician *‘Very difficult to get to them, you need a doctors referral or through your personal connections. Ah, they are very rare – A44033’, ‘Where can I see them... They gave me an appointment after six months – A44011’.*

Lack of awareness of the service was also reported, participants were either not aware of the service or did not know how to approach the service *‘There is no guidance and no awareness – A07128’, ‘I don’t know where to find them – A40043’, ‘I cannot find them, I don’t know where the centres are – AA44053’.* It seemed that participants required some education about the services provided by the health care system *‘You don’t know where they are – A07076’.*

Theme two. Personal and cultural issues

This theme incorporated personal and cultural barriers that emerged as subthemes and they are as following:

1. ‘Resistance to change’ (sub-theme)

Resistance was observed in voice tone, body language and responses. Resistance was very clear among females with no diabetes and they instantly responded by saying *‘I don’t need to – A33275’, ‘I don’t want to and I don’t need to – A33111’, ‘I will not follow the diet that they will give me – A44019’.* Males with no diabetes showed lack of interest *‘I don’t care and don’t look for them – A07020’, ‘I am Saudi! Not keen and reckless – A07003’, ‘I don’t like them – A44108’.* Resistance to change was also associated with lack of need, and God was mentioned in their responses with a more

positive attitude *'Thanks to God nothing happened that required me to do so – A42012', 'I've never came across one and it never occurred to me, thanks to God my health is good and I rarely go to hospitals – A07082'*. This trend was observed among males with diabetes *'Thanks to God the health is good, walking is the best investment – A44042', 'I didn't go, I don't need to thanks to God – A42006', 'Thanks to God, I am fine, thanks to God – A44076'*. Male participants did not need to seek advice because they had other sources of information *'I educate myself, I have some understanding of minerals, carbohydrates, sugars, proteins and I reduce my intake – A07171', 'I take very good care of myself and I always carry out blood tests. I don't need to see dietician because I avoid fast food and fizzy drinks – A44134'*.

2. 'Personal barriers' (sub-theme)

Males with and without diabetes reported personal barriers in three forms, they believed that it is the health care systems responsibility to take this step for them *'Busy life, the doctor did not refer me to one - A07091', 'No one told us to do so – A07125'*. Another barrier was the Saudi culture, they thought it is not culturally appropriate to seek advice from a dietician *'We are not prepared for that, and you feel embarrassed if you request a dietician – A44025', 'Our culture does not allow that, and they did not contact us – A01793'*. Finally, lack of time and work commitment prevented them from seeking advice *'No time and did not have the chance – A44015', 'There is no time, health is precious but we don't give it enough time – A44010'*.

Dietary knowledge

Three questions (questions 4-6) were asked to assess participant's dietary knowledge with regards to diabetes. Deductive (a priori food groups from the Saudi food palm) and inductive (driven from the data) coding were applied. Overall there was no clear difference between groups as food confusion and dietary misconceptions were reported by males and females, participants with and without diabetes, and whether or not they had previously attended a dietary consultation. This section covered three areas and they are as follows:

Question four. Do you know which foods people should eat less of to reduce the risk of getting diabetes?

In general, participants referred to foods falling under this question as 'white food'. The food groups (a priori – deductive themes) reported in this question were fats and sugar, cereal and bread, fruits and meat. The data driven themes (inductive) included dietary habits and dietary misconceptions. Five participants could not answer this question.

1. Deductive themes (from the food palm – a priori food groups)

Participants mentioned fat which included animal fat, cholesterol and fried food. Sugar was reported by the majority of participants and mainly included white sugar (sugar cubes), sweets and fizzy drinks. Cereal and bread was mainly reported using the term 'carbohydrates' and this included white bread, rice and pasta (reported as macaroni). Fruits included dates while meat included eggs, prawns and chicken.

2. Inductive themes (data driven)

Dietary habits included the consumption of fast food and traditional food (such as kabsa and mafateeh – fat dense traditional dishes that include rice and meat/chicken), and some Saudi habits ‘*You eat and sit, I mean you don’t move, restaurant food and chicken kabsa – A07012*’. Participants reported some misconceptions where they believed that the consumption of chicken, oranges, banana, bran or soup should be reduced to prevent diabetes.

Question five. Do you know which foods people should increase to reduce the risk of getting diabetes?

In general, participants referred to foods falling under this question as ‘white meat, brown carbs’. The food groups (a priori – deductive themes) reported in this question were vegetables, cereals and bread, fruits, dairy and meat. The data driven themes (inductive) included dietary habits, dietary misconceptions and food confusion. Forty-one participants could not answer this question.

1. Deductive themes (from the food palm – a priori food groups)

Vegetables included cooked vegetables (called idam in Saudi Arabia) and salad/leafy vegetables (lettuce, spinach and cabbage). Cereal and bread included bran and brown bread. Fruits were mentioned as fruits in general and some mentioned citrus fruits and fresh juice. Dairy included milk and was described as fresh, low fat or no added sugar. Meat included white meat and fish.

2. Inductive themes (data driven)

Dietary habits included the healthy dietary pattern which included decreasing sugar consumption, increasing fibre consumption and increasing physical activity. Boiled food was reported as a method to reduce fat '*Boil the rice to reduce fat – A44050*', '*Boiled food, boiled meat, boiled rice – A42066*'. Some dietary misconceptions were reported such as bitter food and dried food will help in preventing diabetes. Some participants were confused whilst answering, lack of confidence was observed and food confusion (participants reported the same food using different names).

Question six. Do you know what Carbohydrates are?

In general, participants referred to foods falling under this question as 'white carbs'. The food groups (a priori – deductive themes) reported in this question were cereals and bread, fat and sugar, milk and dairy, meat and fruits. The data driven themes (inductive) included dietary patterns, dietary misconceptions and food confusion. Twenty-three participants could not answer this question.

1. Deductive themes (from the food palm- a priori food groups)

Cereals and bread included white bread, rice, potato and pasta (reported as macroni). Fats included olive oil cooking oil and ghee, while sugars included cakes, fizzy drinks and white sugar. Dairy included milk and cheese, while meat included red meat. Fruits included dates which was reported by two participants.

2. Inductive themes (data driven)

Dietary patterns included the traditional diet such as gursan, jereesh and margoog (traditional fat dense dishes). Misconceptions included dry foods, and food confusion was also observed in this section. Food confusion included the repetition of the same

food using different names and the misclassification of foods (ghee and cholesterol were reported as carbohydrates).

C) Section two. Quantitative findings: barriers to healthy eating questionnaire (closed-ended questions)

In this section, the results of the pre-developed and pre-tested questionnaire by Al Quaiz et al. (AlQuaiz and Tayel 2009) are presented for the overall sample, and also stratified by sex and diabetes status. Table 11.7. shows barriers to healthy eating for the overall sample ($n = 108$), and sex stratified results. The factors included in each domain are provided at the end of the table in the footnote. Lack of willpower was a barrier for nearly half of the participants (48.1%), and there was no difference between females (48.0%) and males (48.2%). Similarly, lack of support was reported as a barrier for nearly half of the overall sample, and 47.0% for males and 44.0% for females. Lack of time was ranked third as 36.1% of participants reported time as a barrier to healthy eating. Lack of time was a barrier to 41.0% of males, however it was reported less frequently in females (20.0%). Lack of knowledge and lack of resources were not reported by a high proportion of participants.

Table 11.17. Barriers* to healthy eating for the overall sample

Domain	Overall	Females	Males
Willpower			
Barrier	48.1% (52)	48.0% (12)	48.2% (40)
Not a barrier	51.9% (56)	52.0% (13)	51.8% (43)
Support			
Barrier	46.3% (50)	44.0% (11)	47.0% (39)
Not a barrier	53.7% (58)	56.0% (14)	53.0% (44)
Time			

Barrier	36.1% (39)	20.0% (5)	41.0% (34)
Not a barrier	63.9% (69)	80.0% (20)	59.0% (49)
Resources			
Barrier	10.2% (11)	8.0% (2)	10.8% (9)
Not a barrier	89.8% (97)	92.0% (23)	89.2% (74)
Knowledge			
Barrier	9.3% (10)	0.0% (0)	12.0% (10)
Not a barrier	90.7% (98)	100.0% (25)	88.0% (73)

*Percentages (n); **Lack of willpower** statements: “I lack the motivation to follow a healthy diet”, “I cannot resist traditional food”, “I do not want to follow a healthy diet because I previously failed to do so”; **Lack of support** statements: “I do not follow a healthy diet because I will feel deprived when I look at what others are eating”, “My family do not help/support me to follow a healthy diet”, “Social commitments stops me from following a healthy diet”; **Lack of resources** statements: “Fast food media influence my eating habits”, “I like fast food because it is easy to get”, “I do not buy healthy food because it is expensive and has a short shelflife”; **Lack of time** statements: “I cannot follow a healthy diet because I am away from home for most of the day”, “I was not exposed to enough educational programs to educate me about healthy eating”, “I do not have enough time to prepare healthy meals”; **Lack of knowledge** statements: “I do not want to change my eating habits because I do not have any health problems”, “I do not believe there is a relationship between unhealthy diet and chronic diseases”, “I do not need to eat fruits and vegetables because I take supplements”.

Lack of willpower (47.6%) and lack of support (47.6%) were the main barriers among participants with diabetes. Interestingly, reports on lack of knowledge were the highest among participants with diabetes (16.7%) in comparison to participants with pre-diabetes (9.1%) or no diabetes (3.6%). Figure 11.3. summaries the cultural barriers across diabetes groups. Overall, lack of willpower and support were the main barriers among diabetics, followed by lack of time, lack of knowledge, and finally lack of resources.

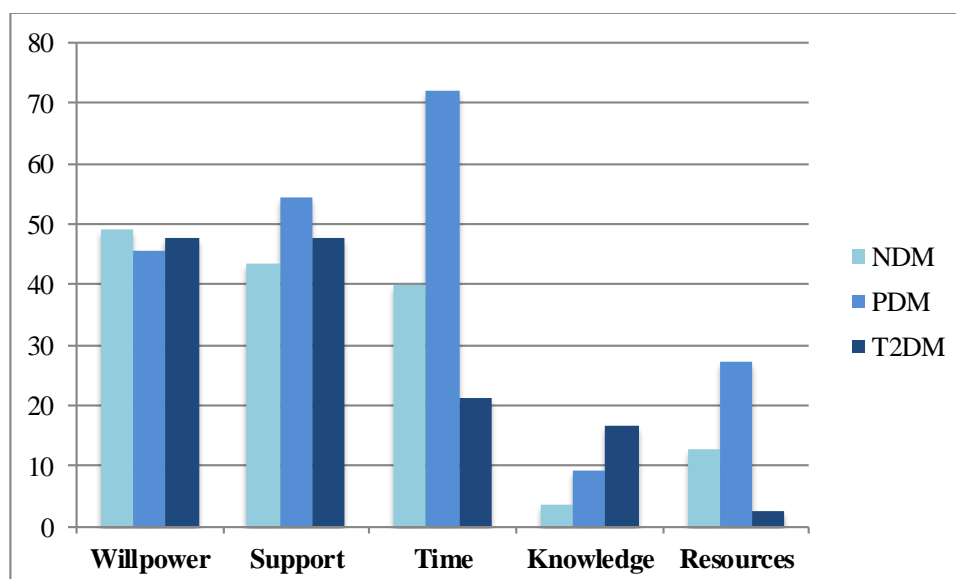


Figure 11.3. Barriers to healthy eating across diabetes groups

Table 11.8. shows the barriers to healthy eating stratified by sex and diabetes groups. Among participants with diabetes, lack of willpower, support and time were the highest in males (44.4%, 50.0%, 22.2% respectively) and females (66.7%, 33.3%, 16.7% respectively). Similar reports were observed among females and males with no diabetes, however, lack of time seemed to be a stronger barrier in males (50.0%) in comparison to females (17.6%).

Table 11.18. Barriers* to healthy eating stratified by sex and diabetes

Domain	Females			Males		
	NDM	PDM	T2DM	NDM	PDM	T2DM
Willpower						
Barrier	41.2% (7)	50.0% (1)	66.7% (4)	52.6% (20)	44.4% (4)	44.4% (16)
Not a barrier	58.8% (10)	50.0% (1)	33.3% (2)	47.4% (18)	55.6% (5)	55.6% (20)
Support						
Barrier	47.1% (8)	50.0% (1)	33.3% (2)	42.1% (16)	55.6% (5)	50.0% (18)
Not a barrier	52.9% (9)	50.0% (1)	66.7% (4)	57.9% (22)	44.4% (4)	50.0% (18)
Resources						
Barrier	11.8% (2)	0.0% (0)	0.0% (0)	13.2% (5)	33.3% (3)	2.8% (1)
Not a barrier	88.2% (15)	100.0% (2)	100.0% (6)	86.8% (33)	66.7% (6)	97.2% (35)
Time						
Barrier	17.6% (3)	50.0% (1)	16.7% (1)	50.0%	77.8%	22.2%
Not a barrier	82.4% (14)	50.0% (1)	83.3% (5)	50.0%	22.2%	77.8%
Knowledge						
Barrier	0.0% (0)	0.0% (0)	0.0% (0)	5.3% (2)	11.1% (1)	19.4% (7)
Not a barrier	100.0% (17)	100.0% (2)	100.0% (6)	94.7% (36)	88.9% (8)	80.6% (29)

*Percentage (n); **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **PDM**: pre-diabetes (FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **T2DM**: type 2 diabetes mellitus (self-reported T2DM or FPG ≥7.0 mmol/L; ≥126 mg/dL); **Lack of willpower** statements: "I lack the motivation to follow a healthy diet", "I cannot resist traditional food", "I do not want to follow a healthy diet because I previously failed to do so"; **Lack of support** statements: "I do not follow a healthy diet because I will feel deprived when I look at what others are eating", "My family do not help/support me to follow a healthy diet", "Social commitments stops me from following a healthy diet"; **Lack of resources** statements: "Fast food media influence my eating habits", "I like fast food because it is easy to get", "I do not buy healthy food because it is expensive and has a short shelf life"; **Lack of time** statements: "I cannot follow a healthy diet because I am away from home for most of the day", "I was not exposed to enough educational programs to educate me about healthy eating", "I do not have enough time to prepare healthy meals"; **Lack of knowledge** statements: "I do not want to change my eating habits because I do not have any health problems", "I do not believe there is a relationship between unhealthy diet and chronic diseases", "I do not need to eat fruits and vegetables because I take supplements".

D) Section three. Dietary misconceptions in T2DM questionnaire (closed-ended questions)

In this section, the results of the modified questionnaire by Sabra *et al.* (Sabra *et al.* 2010) are presented for the overall sample ($n = 108$), sex and diabetes stratified. Table 11.9. shows the prevalence of dietary misconceptions across the overall sample, and separately for females and males. The most prevalent misconception in the overall sample (83.3%), and in females (88.0%) and males (81.9%) was “Regular intake of snacks between meals is essential for adults with type 2 diabetes”.

Over half of the participants (65.7%) thought that bitter food would reduce high glucose levels, and a similar proportion (56.5%) believed that people with diabetes should eliminate carbohydrates from their diet. Nearly half of the participants (43.5%) believed that fruit juice is a better option than consuming whole fruits, and the same proportion thought that drying/toasting bread would reduce sugar content. Figure 11.4. shows the reported dietary misconceptions arranged in ascending order in the overall sample. The majority of participants thought that regular snacking was essential for people with T2DM, while the minority thought that vegetables do not help people with T2DM.

Table 11.19. Dietary misconceptions* for the overall sample

Statement	Overall	Females	Males
<i>People with diabetes that are on medications can eat any type of food</i>			
Misconception	20.4% (22)	12.0% (3)	22.9% (19)
Don't know	7.4% (8)	8.0% (2)	7.2% (6)
No misconception	72.2% (78)	80.0% (20)	69.9% (58)
<i>Dates are very important for the health of people with diabetes</i>			
Misconception	27.8% (30)	20.0% (5)	30.1% (25)
Don't know	11.1% (12)	8.0% (2)	12.0% (10)

No misconception	61.1% (66)	72.0% (18)	57.8% (48)
<i>Honey is good for people with diabetes</i>			
Misconception	39.9% (43)	28.0% (7)	43.3% (36)
Don't know	17.6% (19)	16.0% (4)	18.1% (15)
No misconception	42.6% (46)	56.0% (14)	38.6% (32)
<i>All carbohydrates should be removed from a diabetic diet</i>			
Misconception	56.5% (61)	68.0% (17)	53.0% (44)
Don't know	11.1% (12)	0.0% (0)	14.5% (12)
No misconception	32.4% (35)	32.0% (8)	32.5% (27)
<i>Bitter food will reduce high blood glucose</i>			
Misconception	65.7% (71)	60.0% (15)	67.5% (56)
Don't know	14.8% (16)	20.0% (5)	13.3% (11)
No misconception	19.4% (21)	20.0% (5)	19.3% (16)
<i>Toasted bread contains less sugar than normal bread</i>			
Misconception	43.5% (47)	48.0% (12)	42.2% (35)
Don't know	33.3% (36)	24.0% (6)	36.1% (30)
No misconception	23.1% (25)	28.0% (7)	21.7% (18)
<i>Regular intake of snacks between meals is essential for adults with type 2 diabetes</i>			
Misconception	83.3% (90)	88.0% (22)	81.9% (68)
Don't know	11.1% (12)	8.0% (2)	12.0% (10)
No misconception	5.6% (6)	4.0% (1)	6.0% (5)
<i>Beans, lentils and corn do not contain carbohydrates</i>			
Misconception	27.8% (30)	40.0% (10)	24.1% (20)
Don't know	25.9% (28)	4.0% (1)	32.5% (27)
No misconception	46.3% (50)	56.0% (14)	43.4% (36)
<i>Fresh fruit juice is better than whole fruit for people with diabetes</i>			
Misconception	43.5% (47)	40.0% (10)	44.6% (37)
Don't know	25.0% (27)	20.0% (5)	26.5% (22)
No misconception	31.5% (34)	40.0% (10)	28.9% (24)
<i>Abdominal obesity is not associated with diabetes</i>			
Misconception	18.5% (20)	20.0% (5)	18.1% (15)
Don't know	18.5% (20)	28.0% (7)	15.7% (13)
No misconception	63.0% (68)	52.0% (13)	66.3% (55)
<i>Vegetables will not help in regulating sugar levels in people with diabetes</i>			
Misconception	14.8% (16)	16.0% (4)	14.5% (12)
Don't know	13.0% (14)	8.0% (2)	14.5% (12)
No misconception	72.2% (78)	76.0% (19)	71.1% (59)
<i>There is only one diet people with diabetes should follow</i>			

Misconception	35.2% (38)	48.0% (12)	31.3% (26)
Don't know	12.0% (13)	48.0% (12)	14.5% (12)
No misconception	52.8% (57)	4.0% (1)	54.2% (45)
<i>Portion size is not important for people with diabetes</i>			
Misconception	18.5% (20)	8.0% (2)	21.7% (18)
Don't know	5.6% (6)	8.0% (2)	4.8% (4)
No misconception	75.9% (82)	84.0% (21)	73.5% (61)

*Percentage (n)

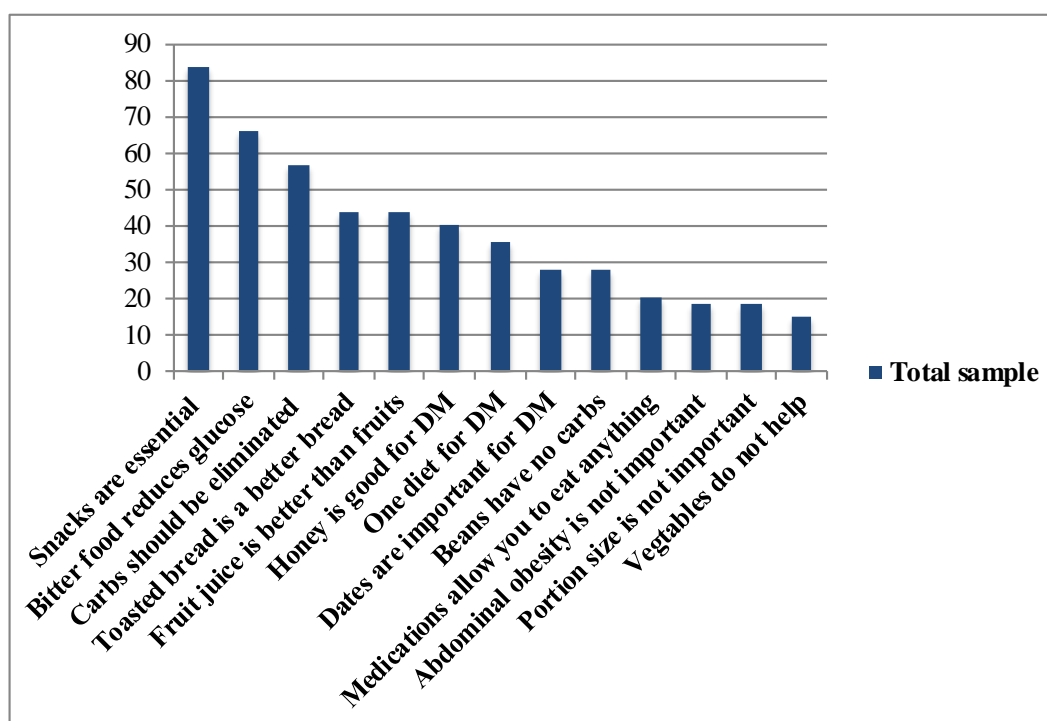


Figure 11.4. Dietary misconception in the overall sample (ascending order)

Table 11.10. shows the prevalence of misconceptions across diabetes groups in both females and males. Participants with NDM reported less dietary misconceptions in comparison to participants with PDM and T2DM. However, regular snacking was thought to be essential for people with T2DM among non-diabetics (88.2% , 78.5% females and males respectively), PDM (100.0% , 77.8% females and males respectively) and T2DM (83.3% , 86.1% females and males respectively).

Over half of females (66.7%) with diabetes thought that a diabetic diet could not be individualized, while all females with PDM thought that beans and lentils do not contain any carbohydrates. A high proportion of males with T2DM (83.3%) believed that bitter food would reduce glucose levels, while 55% of males with PDM thought that people with diabetes should eliminate all carbohydrates from their diet. Figures 11.5. and 11.6. show the main dietary misconceptions in both female and males with T2DM.

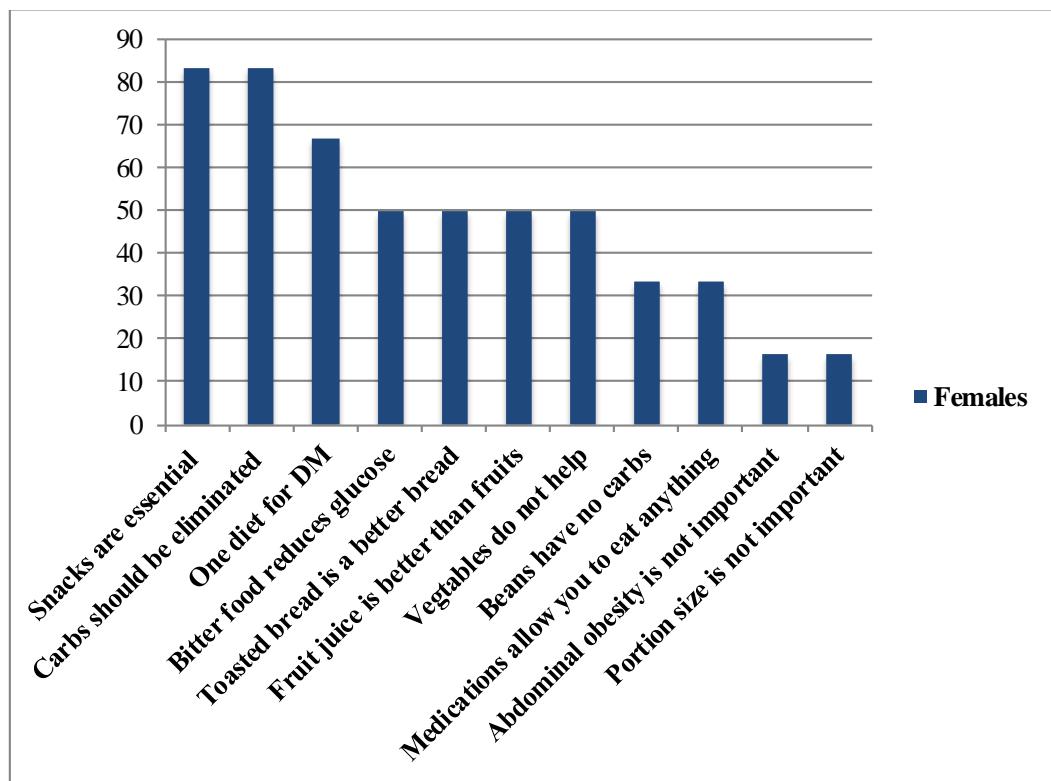


Figure 11.5. Dietary misconceptions in females with diabetes (ascending order)

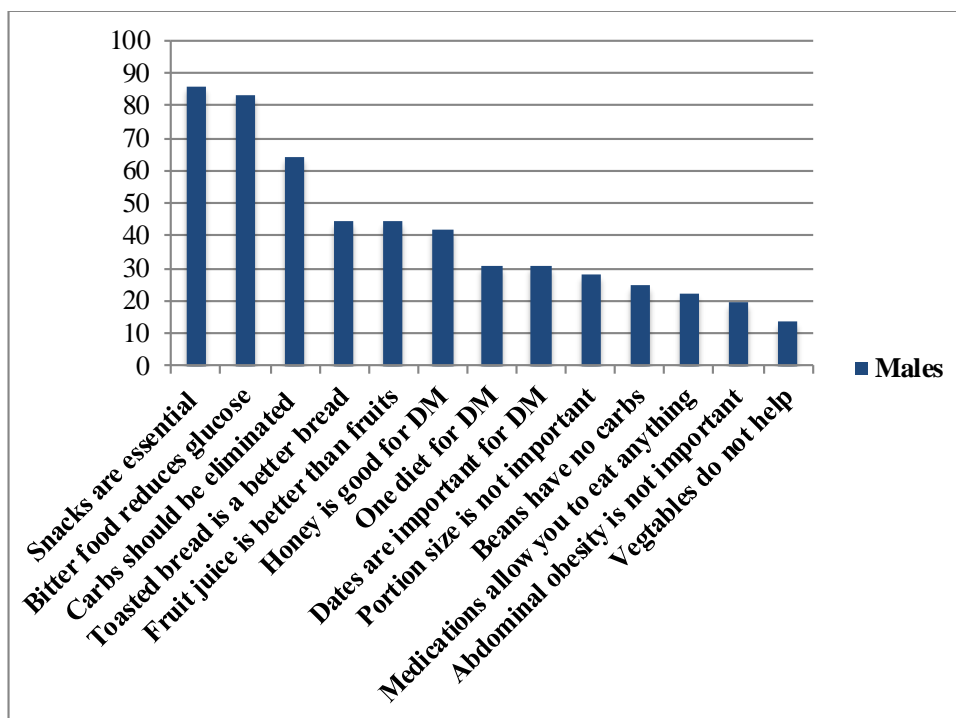


Figure 11.6. Dietary misconceptions in males with diabetes (ascending order)

Table 11.20. Dietary misconceptions* stratified by sex and diabetes

Statement	Females			Males		
	NDM	PDM	T2DM	NDM	PDM	T2DM
<i>People with diabetes that are on medications can eat any type of food</i>						
Misconception	5.9% (1)	0.0% (0)	33.3% (2)	18.4% (7)	44.4% (4)	22.2% (8)
Don't know	5.9% (1)	50.0% (1)	0.0% (0)	7.9% (3)	0.0% (0)	8.3% (3)
No misconception	88.2% (15)	50.0% (1)	66.7% (4)	73.7% (28)	55.6% (5)	69.4% (58)
<i>Dates are very important for the health of people with diabetes</i>						
Misconception	17.6% (3)	100.0% (2)	0.0% (0)	28.9% (11)	33.3% (3)	30.6% (11)
Don't know	11.8% (2)	0.0% (0)	0.0% (0)	15.8% (6)	22.2% (2)	5.6% (2)
No misconception	70.6% (12)	0.0% (0)	100.0% (6)	55.3% (21)	44.4% (4)	63.9% (23)
<i>Honey is good for people with diabetes</i>						
Misconception	41.2% (7)	0.0% (0)	0.0% (0)	44.7% (17)	44.4% (4)	41.7% (15)
Don't know	0.0% (0)	100.0% (2)	33.3% (2)	18.4% (7)	22.2% (2)	16.7% (6)
No misconception	58.8% (10)	0.0% (0)	66.7% (4)	36.8% (14)	33.3% (3)	41.7% (15)
<i>All carbohydrates should be removed from</i>						
Misconception	58.8% (10)	100.0% (2)	83.3% (5)	42.1% (16)	55.6% (5)	63.9% (23)
Don't know	0.0% (0)	0.0% (0)	0.0% (0)	18.4% (7)	22.2% (2)	8.3% (3)
No misconception	41.2% (7)	0.0% (0)	16.7% (1)	39.5% (15)	22.2% (2)	27.8% (10)
<i>Bitter food will reduce high blood glucose</i>						
Misconception	58.8% (10)	100.0% (2)	50.0% (3)	60.5% (23)	33.3% (3)	83.3% (30)
Don't know	17.6% (3)	0.0% (0)	33.3% (2)	10.5% (4)	44.4% (4)	8.3% (3)
No misconception	23.5% (4)	0.0% (0)	16.7% (1)	28.9% (11)	22.2% (2)	8.3% (3)
<i>Toasted bread contains less sugar than normal</i>						

Misconception	47.1% (8)	50.0% (1)	50.0% (3)	42.1% (16)	33.3% (3)	44.4% (16)
Don't know	17.6% (3)	50.0% (1)	33.3% (2)	34.2% (13)	44.4% (4)	36.1% (13)
No misconception	35.3% (6)	0.0% (0)	16.7% (1)	23.7% (9)	22.2% (2)	19.4% (7)
<i>Regular intake of snacks between meals is essential for adults with type 2 diabetes</i>						
Misconception	88.2% (15)	100.0% (2)	83.3% (5)	78.9% (30)	77.8% (7)	86.1% (31)
Don't know	5.9% (1)	0.0% (0)	16.7% (1)	13.2% (5)	22.2% (2)	8.3% (3)
No misconception	5.9% (1)	0.0% (0)	0.0% (0)	7.9% (3)	0.0% (0)	5.6% (2)
<i>Beans, lentils and corn do not contain carbohydrates</i>						
Misconception	35.3% (6)	100.0% (2)	33.3% (2)	21.1% (8)	33.3% (3)	25.0% (9)
Don't know	0.0% (0)	0.0% (0)	16.7% (1)	28.9% (11)	33.3% (3)	36.1% (13)
No misconception	64.7% (11)	0.0% (0)	50.0% (1)	50.0% (19)	33.3% (3)	38.9% (14)
<i>Fresh fruit juice is better than whole fruit for people with diabetes</i>						
Misconception	41.2% (7)	0.0% (0)	50.0% (3)	50.0% (19)	22.2% (2)	44.4% (16)
Don't know	11.8% (2)	50.0% (2)	33.3% (2)	18.4% (7)	55.6% (5)	27.8% (10)
No misconception	47.1% (8)	50.0% (2)	16.7% (1)	31.6% (12)	22.2% (2)	27.8% (10)
<i>Abdominal obesity is not associated with diabetes</i>						
Misconception	17.6% (3)	50.0% (1)	16.7% (1)	15.8% (6)	22.2% (2)	19.4% (7)
Don't know	29.4% (5)	50.0% (1)	16.7% (1)	15.8% (6)	0.0% (0)	19.4% (7)
No misconception	52.9% (9)	0.0% (0)	66.7% (4)	68.4% (26)	77.8% (7)	61.1% (22)
<i>Vegetables will not help in regulating sugar levels in people with diabetes</i>						
Misconception	0.0% (0)	50.0% (1)	50.0% (3)	13.2% (5)	22.2% (2)	13.9% (5)
Don't know	5.9% (1)	0.0% (0)	16.7% (1)	10.5% (4)	0.0% (0)	22.2% (8)
No misconception	94.1% (16)	50.0% (1)	33.3% (2)	76.3% (29)	77.8% (7)	63.9% (23)
<i>There is only one diet people with diabetes should follow</i>						
Misconception	41.2% (7)	50.0% (1)	66.7% (4)	31.6% (12)	33.3% (3)	30.6% (11)

Don't know	5.9% (1)	0.0% (0)	0.0% (0)	13.2% (5)	0.0% (0)	19.4% (7)
No misconception	52.9% (9)	50.0% (1)	33.3% (2)	55.3% (21)	66.7% (6)	50.0% (18)
<i>Portion size is not important for people with diabetes</i>						
Misconception	0.0% (0)	50.0% (1)	16.7% (1)	15.8% (6)	22.2% (2)	27.8% (10)
Don't know	0.0% (0)	0.0% (0)	33.3% (2)	5.3% (2)	11.1% (1)	2.8% (1)
No misconception	100.0%	50.0% (1)	50.0% (3)	78.9% (30)	66.7% (6)	69.4% (25)
	(17)					

*Percentages (n); **NDM:** non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **PDM:** pre-diabetes (FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **T2DM:** type 2 diabetes mellitus (self-reported T2DM and/or FPG ≥7.0 mmol/L; ≥126 mg/dL).

11.2.4. Discussion

The current study aimed to identify barriers to healthy eating among Saudi individuals using qualitative and quantitative approaches. Overall, three emerging themes were identified; health benefits, lack of knowledge and cultural issues. Constant comparison showed a difference in the perception of health, diet and cultural issues among participants (males vs. females, diabetics vs. non-diabetics). Lack of willpower and social support were the main barriers among participants and they were expressed in different ways.

Health was perceived differently across sexes, females were concerned about body weight while males focused on maintaining current health in general. Obesity is a public health problem in Saudi Arabia, and around 44% of Saudi females are obese (Al-Nozha et al. 2005). A recent study by Al Musaiger *et al.* showed that 65% of Arab females preferred a thinner body size (Musaiger 2013). The findings of the current study showed that Saudi females were aware of their weight problem, preferred to lose weight and believed that healthy eating will reduce their body weight. The majority of females seemed to be in the contemplation stage, they acknowledged the problem but had barriers that prevented them from taking action (Sporny et al. 1995). The main barriers among females were resistance to change and lack of willpower, they thought that they did not need to or were not ready for dietary modification. They showed a negative attitude in both body language and voice tone towards health care professionals who delivered lifestyle modification ‘i.e. *I don’t like them, I will not follow what they will tell me*’. Two factors may have contributed to these barriers, lack of knowledge and lack of communication.

In this study, lack of knowledge was observed when females thought that healthy eating included only fruits and vegetables. Therefore, females may refuse to take action because they lack the knowledge of what healthy eating consists of and how it can be individualized to meet their needs. Previous studies reported lack of communication between patients and health care professionals in Saudi health care settings (Mobeireek et al. 1996, Al-Doghaither et al. 2000, Saeed et al. 2001). Motivational interviewing, patient involvement, and readiness to change are crucial factors for successful dietary modification (Kasila et al. 2003), however, this is not offered in the Saudi health system. It has been reported that Saudi patients complained about lack of communication and patient involvement in their treatment plan (Saeed et al. 2001). This may explain the negative attitude that females had towards health educators that would eventually prevent them from seeking advice on dietary modification.

Additionally, lack of communication may also explain the food confusion that was reported by diabetics and non-diabetics who had received previous dietary consultation. Saudi patients have been shown to be dissatisfied with healthcare professionals interpersonal skills, such as listening to patients complaints and appreciating the reason for the consultation/visit (Saeed et al. 2001). The quantitative data from the second and third parts of the questionnaire showed that lack of knowledge was higher amongst participants with diabetes in comparison to other groups. It is possible that the delivered dietary message has not been clear enough for patients to understand. It is also possible that the dietary message is not tailored to patients needs and therefore they will not listen, absorb and apply the information.

Hyperglycemia is prevalent among Saudi's with type 2 diabetes and only 27% achieve glycemic control (Azab 2001). Hyperglycemia was a concern among males with

diabetes and they associated healthy eating with glucose control. The majority of males with diabetes were referred to a dietician for glucose control, and only two participants took action and personally requested dietary modification. Although males with diabetes perceived health as precious and irreplaceable, the main barrier was lack of need which was associated with a positive attitude towards their current health condition. Saudi nationals practice Islam as a religion, and they have a strong and unquestionable faith in God. Saudis believe that health, disease and death is Gods will, therefore they believe that illness is a predestination from God and it will erase a person's sins (Aldossary et al. 2008). This attitude was clearly observed among males with diabetes, they showed a positive attitude towards their current health as they constantly thanked 'Allah - God' with a smile on their face.

On the other hand, males with no diabetes associated healthy eating with better health in general, healthy eating mattered to them because they were getting older. Gough et al. reported a similar observation among males in the UK where age was a factor when considering dietary changes (Gough et al. 2006). From the qualitative data, the main barrier amongst males without diabetes was lack of interest, in line with the quantitative data where lack of willpower was a major barrier amongst this group. Males with no health issues found it very difficult to consult a health educator because of limitations in the health system (physicians referral, lengthy process, lack of staff). They expressed in body language, voice tone and verbal response their anger and dissatisfaction with the health services. Primary health care centres in Riyadh have a shortage in health education staff (Asiri et al. 2013) and a physician referral is required to access this service (Saeed et al. 2001). Another factor that may be associated with the lack of interest is lack of social support, which was a barrier to 47% of males in this study. In another study conducted in 144 Saudi males, lack of social support, which includes

family and social pressure, was a barrier for 69.3% of participants (AlQuaiz and Tayel 2009). Hospitality is a strong feature of the Saudi culture, it is not linked to social class or wealth in Saudi Arabia. Frequent social occasions such as family gatherings and weddings require displays of hospitality which mainly include large amounts of food. Hospitality in Saudi Arabia includes extensive greetings, insistence, emphasis, and assistance to join their occasion (Ellen 1997). Males complained about the pressure/insistence to over eat in social occasions, if they had to cave into this pressure for social occasions then why bother to eat healthily at other times.

Lack of knowledge was a barrier among participants and there was no difference across groups (females vs. males, diabetics vs. non-diabetics, seen a dietician vs. did not). Although the quantitative data showed that lack of knowledge was not reported as a frequent barrier, it assessed different aspects of knowledge (i.e. the relationship between diseases and healthy eating, supplements replace fruits and vegetables). Nevertheless, lack of knowledge was higher among males with diabetes (19.4%) in comparison to non-diabetics (5.3%). The qualitative data showed that participants struggled to answer questions or expressed lack of knowledge in different forms such as misconceptions and food confusion.

Participants, who had previously consulted a dietician, thought that dry food and bitter food were good for diabetes. The same reported misconceptions in this study have been reported in a previous study that assessed dietary misconceptions in 1039 Saudi diabetics. The study showed that over 53% of diabetics thought that bitter food and dried bread is good for diabetes (Al-Saeedi et al. 2002). These results are in line with the current study where 65.7% of participants thought that bitter food will reduce blood sugar and 43.5% thought that toasted bread contains less sugar. Dietary confusion was

clear amongst participants, for instance cheese and olive oil were reported as carbohydrates. The majority believed that dates should be reduced to prevent diabetes, however, only two participants identified dates as a carbohydrate containing food. Participants did not seem to have a clear understanding of portion size, portion control was perceived as not being very full. In Saudi Arabia, eating with hands is a common practice and especially during social occasions (Sharif et al. 2010). Nearly a quarter of males thought that portion size was not important in a diet. Therefore, Saudi individuals may not have a clear understanding of portion/serving size.

Reliance was reported by the majority of participants and especially by males. The findings indicated that participants thought that illness or health is a predestination from God. Participants believed that it is not their responsibility to take action and they relied on the health care system to identify their health needs and manage their health issues. Reliance may be a consequence of lack of patient awareness, involvement and effective communication between health care providers and patients (Mobeireek et al. 1996, Saeed et al. 2001). It has been reported that primary health care attendees in Saudi Arabia were not fully aware of health educators role (Asiri et al. 2013). Some participants were not aware of the available services while others did not know how to access this service.

Summary

In this section, the barriers to healthy eating of a sub-sample ($n = 108$) of the original survey (2009) have been presented. The questionnaires used in this study consisted of three sections. The first section included six open-ended questions which were developed for the current study, the second section was the AlQuaiz et al. questionnaire

(AlQuaiz and Tayel 2009), and the third section was a modified version of Sabra *et al.* questionnaire (Sabra et al. 2010). In the next chapter, the final discussion of this thesis will be presented.

12 Discussion

Introduction

In this chapter, the main findings from each section of this thesis in relation to the aims and objectives are presented. A summarised discussion of the relationship between the main findings and the results of previous research are presented. The strengths and limitations of the current project are presented, and the implications for policy, practice and future research are discussed and a broad conclusion is presented. Finally, the scientific outputs of this project are listed.

12.1. Principal findings of this project

In brief, this project was part of an ongoing collaboration between Warwick Medical School and the investigators of the Biomarkers Screening in Riyadh survey (2009). The 2009 survey was launched to identify novel biomarkers of chronic non-communicable diseases amongst consenting Saudi nationals. More than 14,000 consenting participants joined the survey and demographic data and blood samples were collected. A sub-sample ($n = 2631$) completed a food frequency questionnaire which this project had access to.

The literature review showed that diabetes is a major public health concern affecting 8.3% of the world population and especially the Middle Eastern region (Shaw et al. 2009, Shaw et al. 2010, Guariguata et al. 2013). Saudi Arabia is within the top ten countries for the highest prevalence of diabetes and is expected to rank sixth by 2035

(Guariguata et al. 2013). Local studies from Saudi Arabia have perceived diabetes to be a major epidemic where the prevalence of diabetes increased from 2.5% in the 1980's to 31.6% in 2011 (Bacchus et al. 1982, Al-Daghri et al. 2011). Despite the striking prevalence of diabetes amongst Saudi Adults, cultural specific risk factors, specifically dietary factors, have been poorly evaluated. The associations between anthropometric measures and T2DM, mainly BMI, originate from unadjusted analyses (Al-Nozha et al. 2004, Al-Daghri et al. 2005, Al-Daghri et al. 2011). The magnitude of the association between anthropometric measures and the prevalence of T2DM has not been extensively studied within the Saudi context (Ng et al. 2011). Diet-related chronic conditions, such as diabetes, represent a major public health concern in Saudi Arabia (Musaiger 2004, Al-Othaimeen et al. 2007, Elhadd et al. 2007). The nutritional transition, mainly attributed to the oil boom, has shifted dietary intake from wheat, legumes and vegetables to energy dense-fatty diet (Al-Shoshan 1992). However, evidence linking these dietary habits to the emerging diabetes epidemic has not been clearly defined within the Saudi context and studies examining the diet-diabetes association are very scarce (Nielsen 1999, Al Majwal et al. 2009, Ng et al. 2011, Amini et al. 2012).

Local studies have suggested that some micronutrients might be associated with diabetes in Saudi adults. Extremely low vitamin D levels have been reported amongst Saudi adults (Sedrani 1984, Al-Daghri et al. 2010, Elsammak et al. 2010, Al-Daghri et al. 2011). International studies have reported an inverse association between vitamin D levels and T2DM (Scragg et al. 1995, Pittas et al. 2007, Scragg 2008), however, this has not been extensively explored among Saudi adults (Al-Daghri et al. 2010). Although Saudi adults suffer from low vitamin D levels (Al-Daghri et al. 2010) and low vitamin D dietary intake (Al-Assaf and Al-Numair 2007), the association with diabetes

prevalence remains unclear within the Saudi context. On the other hand, recent reports have shown that Saudi adults have high intakes of dietary selenium (75-122 µg/person/day) (Al-Ahmary 2009) and the mean levels of serum selenium are comparable to selenium replete populations (Gibson et al. 1985, Bleys et al. 2007, Obeid et al. 2008). International findings reported an adverse effect of high selenium status on the risk of T2DM (Stranges et al. 2010, Rees et al. 2013). However, this remains unclear amongst Saudi individuals with high selenium intakes.

Finally, the literature review identified some cultural specific barriers that might be associated with poor dietary habits. Lack of dietary knowledge (Sabra et al. 2010) and lack of willpower to improve dietary habits (AlQuaiz and Tayel 2009, Bakhotmah 2012) were common barriers amongst Saudi individuals. However, it is difficult to extrapolate these factors to adults with diabetes since previous studies did not sufficiently explore barriers within Saudi diabetic populations.

A systematic review was conducted to identify and synthesise the available evidence on the association between dietary factors and T2DM in Middle Eastern populations. Despite thorough and extensive searching, relatively few ($n = 17$) studies were identified and only one study originated from Saudi Arabia. The Saudi study was a case-control study and the exposure was specific food items, with no justification for the chosen foods. The nutritional analysis was not clearly defined and adjustment for dietary covariates was not accounted for. Overall, the data were not sufficient to identify cultural specific dietary factors associated with the risk of T2DM in the Middle Eastern population in general and Saudi Arabia specifically.

The descriptive analyses of the overall sample of this project ($n = 2631$) showed a high prevalence of T2DM (29.3%). Subgroup analysis identified some socio-demographic,

anthropometric and lifestyle characteristics that might be associated with diabetes and have not been previously explored within the Saudi context. Waist to hip ratio and sagittal abdominal diameter were significantly higher amongst females and males with diabetes in comparison to pre and non-diabetics. Interestingly, the highest marriage rate was amongst females and males with diabetes (77.2% and 92.7% respectively) whilst the highest prevalence of being single was amongst non-diabetics. There was no significant difference in consanguineous marriages amongst sex stratified diabetes groups. Finally, diabetics had the least sleeping time in comparison to other groups and females with diabetes had higher reports of disrupted sleeping patterns.

In this project, the associations between dietary factors (anthropometric measures, dietary items and nutritional biomarkers) and T2DM were examined for the first time amongst Saudi adults with and without T2DM using multivariate analysis. Firstly, the associations between anthropometric measures and T2DM were explored in this study in participants with and without T2DM, a subsample ($n = 2355$) of the original cohort ($n = 2631$). The logistic regression analysis in the overall sample showed that the association between anthropometric measures and T2DM was the highest for WC (OR 2.41, 95% CI, 1.6-3.4), then BMI (OR 2.08, 95% CI, 1.4-3.0), WHR (OR 1.84, 95% CI, 1.3-2.6) and finally SAD (OR 1.71, 95% CI, 1.2-2.5). The sex-specific associations showed that BMI (≥ 30 kg/m²) remained significantly associated with T2DM in females after adjustment for covariates (OR 3.39, 95% CI, 1.5-7.6). In males, WC (OR 1.99, 95% CI, 1.2-3.1), WHR (2.02, 95% CI, 1.2-3.0) and SAD (OR 1.79, 95% CI, 1.1-2.8) remained significantly associated after adjustment for potential confounders. Most importantly, a direct and statistically significant association between the age-sex adjusted OR for diabetes and WC persisted within each group of BMI in the overall sample. However, this association attenuated between BMI and diabetes across tertiles

of WC. Moreover, the associations of central adiposity, indicated by WC, with diabetes were independent of BMI, whereas the opposite was not true.

The food frequency questionnaire used in the 2009 survey was tested against two 24-hour dietary recalls in a sub-sample ($n = 98$) of the original cohort ($n = 2631$). The current study is the first study which attempts to validate a food frequency questionnaire in Saudi Arabia. The crude correlations between the two dietary tools showed reasonable agreement (r ranged from 0.302-0.619). Correlation coefficients decreased after energy adjustment for the majority of the dietary items. This decrease indicated that variability of the dietary items depended on measurement error rather than energy intake. The variance ratio of within- to between person variance was greater than one for most foods, where within person variance was usually higher due to daily dietary intake variation. However, date and coffee intakes were not affected by day to day variation as the within individual variation was lower than between individuals variation. Adjustment for measurement error, within and between person variance, improved the correlations (r ranged from 0.416-0.815). Therefore, adjustment for energy intake and measurement error when reporting diet-disease relationships relying on food frequency questionnaires is extremely important to increase the accuracy of the associations.

Secondly, the association between selected food and beverage items and T2DM were explored in this study. The associations were examined in participants who were not aware of their diabetes (at the time of the 2009 survey) and non-diabetics, a subsample ($n = 1867$) of the original cohort. The results showed that participants who were unaware of their diabetes reported a higher consumption of white breads, brown bread, egg, sugar/honey and fruits in comparison to non-diabetics. On the other hand, participants

who were unaware of their diabetes reported lower intake of dates in comparison to non-diabetics. An interesting significant inverse association was observed between date consumption and T2DM in the overall sample after adjusting for covariates and correcting for measurement error (OR 0.19, 95% CI, 0.1-0.6). The sex stratified analysis showed a significant inverse association between date consumption and diabetes in both sexes. However, this association remained significant in males but not in females, likely as a result of limited statistical power in subgroup analyses.

Thirdly, the association between dietary biomarkers (vitamin D and selenium) and T2DM were examined. The sex-diabetes stratified subsample ($n = 567$) was randomly generated from the original cohort ($n = 2631$). The associations between covariates and vitamin D levels were explored. An inverse association was observed between vitamin D levels and education level ($r = -0.118$, $p = 0.008$). On the other hand, egg consumption was positively associated with vitamin D levels ($r = 0.135$, $p = 0.007$). Analysis of covariance showed that mean levels of vitamin D were higher amongst participants who were unaware of their diabetes in comparison to non-diabetics. However, these observations reached a formal level of statistical significance ($p = 0.018$) in females but not males. Nonetheless, the adjusted mean values of vitamin D levels in the diabetes group were low (25.41 in females, 32.88 in males).

On the other hand, selenium levels were high in the subsample (mean=104.35 ng/ml). The associations between covariates and serum selenium showed a significant association with fasting insulin ($r = 0.110$, $p = 0.011$) and TG-C ($r = 0.124$, $p = 0.004$) in the overall sample. However, fasting insulin remained significantly correlated with selenium in males but not females, whilst lipid parameters were significantly correlated with selenium in females but not in males. Most importantly, participants in the diabetes

group had higher levels of selenium in comparison to non-diabetics. However, the adjusted mean levels showed no significant difference between selenium levels in diabetics and non-diabetics. Therefore, no association was observed between high selenium levels and T2DM.

Finally, cultural barriers to healthy eating in Saudi adults, with and without T2DM were explored in this project. A subsample ($n = 108$) of the original cohort ($n = 2631$) were invited to take part in this study. Piloting the questionnaire improved the structure and content of the questionnaire. Moreover, the pilot study informed the analysis plan for this study. Cultural barriers were assessed using qualitative and quantitative methods. Overall, three emerging themes were identified; health benefits, lack of knowledge and cultural issues. Health, diet and cultural issues were perceived differently amongst females in comparison to males, and in diabetics in comparison to non-diabetics. Females associated health with low body weight whilst males focused on health maintenance. Males with diabetes were concerned about hyperglycemia. Both qualitative and quantitative data showed that the main barrier was lack of willpower.

Females demonstrated a negative attitude, in body language, voice tone and response towards health care professionals who deliver lifestyle modification. Males with no diabetes showed a lack of interest. Both qualitative and quantitative data showed that lack of knowledge was a barrier amongst females and males, diabetics and non-diabetics and most interestingly amongst participants who were previously exposed to dietary consultation. Lack of knowledge incorporated dietary misconceptions and food confusion. Whilst some participants struggled to provide an answer to the question asked. Females thought that healthy eating included only fruits and vegetables. Lack of knowledge was higher amongst males with diabetes (19.4%) in comparison to non-

diabetics (5.3%). Participants who had previously consulted a dietician thought that dry food and bitter food were good for diabetes. Participants thought that cheese and olive oil were carbohydrates which indicated food confusion. Cultural issues included reliance on God and the health care system. Participants with diabetes thanked God for their current health condition. The majority of participants relied on the health care system to take care of their current health and initiate lifestyle modification. Males complained about the social pressure to over eat in social occasions. Overall, there was a clear dissatisfaction with the available health care services, specifically, dietary modification. Participants complained about the lengthy and difficult process of accessing dietary modification services.

12.2. Strengths and limitations of this project

The study relied on an extensive literature review of Saudi Arabian studies to arrive to the aims and objectives for this project. The cross-sectional nature of this study can only suggest possible associations between the exposure and outcome. Therefore, causality or temporal relationship cannot be established (Gordis 2008). Residual confounding and reverse causation could not be completely eliminated from the observed associations. However, analysis was balanced with sensitivity approaches to minimise reverse causality (Lawlor et al. 2006).

The sample of this project was a subsample ($n = 2631$) of the original 2009 cohort ($n > 14000$) who were randomly selected from the roster of 150 primary health care centres of Riyadh city, Saudi Arabia. For each primary health care centre, a physician invited participants from randomly selected households (alternate houses). The number of

subjects collected from each centre was dependent on the total population assigned to the respective primary health care centre.

The data used in this project was previously collected by the Biomarkers Screening in Riyadh survey (2009), the collaborators for this project. Therefore, this project relied on pre-collected data, tools and methods as applied in the 2009 survey. Adjustment for potential confounders was informed by the unadjusted descriptive analyses and the literature. Misreports in the pre-collected data, mainly smoking in this project, prevented the adjustment for further potential confounders. Primary health care physicians completed the questionnaires and trained research nurses collected demographic, anthropometric, physiological and biochemical data. Diabetes diagnosis was confirmed by self-report of primary health care physician diagnosis and/or anti-diabetes medication, and/or WHO cut offs for the newly diagnosed; T2DM with a FPG of ≥ 7.0 mmol/L (126 mg/dL); IFG with a FPG between 6.1-6.9 mmol/L (110-125 mg/dL); and non-diabetics with a FPG of < 6.1 mmol/L (110 mg/dL) (WHO 2006).

The Saudi collaborators provided a dataset of 3248, however, 15 cases were duplicates, 64 had type 1 diabetes, 9 had gestational diabetes and 529 had no dietary data. The inclusion criteria for this study was to include participants with dietary data (from the FFQ) to adjust for dietary covariates in multivariate analysis. Significant differences in selected characteristics between participants with and without dietary data were observed. This difference is a potential limitation which is likely to introduce some selection bias. Interestingly, participants with no dietary data ($n = 529$) were generally healthier, this could also partially explain the high prevalence of diabetes (29.9%) observed in this study, which could be an overestimation as healthier participants were not included (due to unavailable dietary data). Larger differences could have been

detected for some of the observed associations (i.e. with anthropometrics) by including these additional participants ($n = 529$), however, adjusting for energy intake would not have been possible.

The poor structure of a number of the FFQ questions and dietary misreports hugely affected the available dietary data. Consequently, a great loss of dietary data occurred in this study which is likely to introduce selection bias and affect the overall associations between dietary items and diabetes. However, every effort was made to follow thorough methods in assessing the diet-diabetes association (Willett 1998). The FFQ was validated against two 24-hour dietary recalls to ensure accurate dietary measurements. The validation sample was an internal subsample of the original cohort. Sex-stratification would have been ideal in the calibration study, however, this was not possible because of the very few numbers of female participants ($n = 22$) and the risk of reporting spurious associations. Most importantly, measurement error was accounted for in the analysis (both calibration and food/beverage items) which improved the observed associations (Freedman et al. 2011). The associations between selected food/beverage items were explored in participants with newly diagnosed T2DM and non-diabetics. The inclusion of participants with newly diagnosed diabetes was to minimise reverse causality (Lawlor et al. 2006).

For the dietary biomarkers laboratory analysis (vitamin D and selenium), 33 serum samples were not available and therefore the sample reduced from 600 to 567. Nonetheless, the sample was randomly generated from the original cohort ($n = 2631$) and was stratified by sex and glycaemic status. The survey did not collect data on osteoporosis or osteoporosis therapy which would have been ideal to better understand the observed associations between vitamin D levels and diabetes in females. The pilot

of the cultural barriers to healthy eating questionnaire greatly improved the structure, content and analytic approaches used in this study.

Finally, challenges during the fieldwork in Saudi Arabia affected the selection criteria of participants in both the FFQ calibration and cultural barriers to healthy eating studies. A random sub-sample, sex and glycaemic stratified, generated from the original cohort of this project ($n = 2631$) would have been ideal. However that was not feasible because of the following reasons:

- The time frame of the fieldwork allowed by the funding body of this project was three months only.
- This project was granted £ 24,000, therefore, research expenses were restricted to the available funding.
- The original cohort was distributed across different primary health care centres in Riyadh and travelling to these centres was not feasible.
- At the time of the fieldwork, six primary health care centres were collaborating with the Biomarkers Research Screening program. Hence, the centres were chosen because of readily available resources (i.e. research nurses).
- The method of communication between primary health care centres and registered citizens is telephone calls. The recall of participants relied upon availability of valid telephone numbers collected in the 2009 survey. It would have been ideal if the 2009 survey collected file numbers of participants to compensate for missing/wrong telephone numbers.
- There were 345 potential participants in the six primary health care centres. A large number was lost (160 of the 345) because of unavailable telephone numbers.

- Cultural restrictions affected the process of recalling participants. For instance, primary health care centres in Saudi Arabia consist of two separate sections, a female section and a male section. In some primary health care centres I was not allowed access to the male section, being a female, and that reduced the number of potential participants.
- During the fieldwork period, one research nurse resigned and the process of inviting potential participants was hugely delayed at that primary health care centre.
- The main reason that females could not participate in this study was because of travelling restrictions. Females relied on their male companions to drive them to their local primary health care centre as they are not allowed to drive in Saudi Arabia.

12.3. Comparison with previous studies

The systematic review confirmed the lack studies on the association between dietary factors and T2DM in the Middle Eastern region in general and Saudi Arabia specifically. Previous local studies have emphasized the need for dietary studies in Saudi populations to better understand the association between dietary risk factors and the diabetes epidemic in this population (Al-Nuaim 1997, Al-Nozha et al. 2004, Al-Othaimeen et al. 2006). The prevalence of glucose abnormalities in this study was high, and the prevalence of T2DM was 29.3% which is comparable to recent local diabetes estimates. The most recent study on diabetes prevalence was conducted in Riyadh, where this current project was conducted. The study included 9149 Saudi individuals and the prevalence of diabetes was 31.6% (Al-Daghri et al. 2011). However, comparability should be carried out with caution since the study included a different age

range (7-80 years) in comparison to this current project (≥ 18 years). Additionally, diabetes diagnosis was based on FPG values only (Al-Daghri et al. 2011), whilst in the present study both self-report of a physician diagnosis and use of anti-diabetes medication were also included as diagnostic criteria for T2DM. Global estimates of diabetes prevalence have reported an overall prevalence of 24% amongst Saudi adults aged 20-79 years (Guariguata et al. 2013). Diabetes prevalence was estimated from several local Saudi studies reporting the age-specific prevalence for diabetes, and used the Analytic Hierarchy Process to systematically select studies to generate estimates. However, the analysis and age group used in Guariguata et al. study was different to the current study.

Although SAD is associated with diabetes (Anjana et al. 2004), diabetes markers (Risérus et al. 2004), and diabetes risk factors (Valsamakis et al. 2004) in other contexts, it has not been extensively explored as a risk factor for T2DM in Saudi (Al-Nozha et al. 2004, Al-Daghri et al. 2011), Gulf countries (Al-Riyami and Afifi 2003) and Middle Eastern countries (Balkau et al. 2007, Esteghamati et al. 2009). The results showed that the mean values of SAD were 23.9 cm. SAD increased significantly across diabetes groups and were higher in males in comparison to females. One Saudi study which presented the mean values of SAD in 72 participants with metabolic syndrome and 113 without metabolic syndrome found no significant difference between the two groups (26.1 cm, 23.1 cm respectively) (Al-Daghri et al. 2013). However, the small sample size and lack of sex stratification makes it difficult to compare to the current study.

Females in the current study had a slightly higher SAD in comparison to female Middle Eastern immigrants in Sweden (22 cm) (Petersson et al. 2007). Amongst Asian Indians

SAD was found to be significantly higher amongst diabetics (22.6 vs. 21.0 cm) (Anjana et al. 2004). The SADs reported in the current study are however higher in comparison to Indians.

The mean values of WHR were 0.90 for the overall sample, which is similar to the mean values of WHR in the Middle Eastern region (0.92) (Musaiger 2011). Males had a significantly higher WHR ($p < 0.001$) in comparison to females, 0.94 compared to 0.85 respectively. Neighbouring countries in the Gulf region, such as Oman, report similar findings. The mean WHR in Omani adults is 0.91, and females have a significantly lower WHR in comparison to males across different age groups (Al-Riyami and Afifi 2003). The WHR of US adults (0.90) is comparable to this study sample (Li et al. 2010). However, Saudi adults have higher WHR when compared to other countries in the Middle East, the WHR of Iraqi females is 0.81 (Al-Tawil et al. 2007), 0.92 in Palestinian males, and 0.81 for females (Abdul-Rahim et al. 2001). Africans have a lower WHR (0.84 for males, 0.80 for females) in comparison to Saudi adults (Okosun et al. 1998). When comparing to the WHO cut-offs for metabolic risk (≥ 0.90 for males, ≥ 0.85 cm for females), Saudi adults may have a substantially increased risk for metabolic disorders (WHO 2011). Adults with diabetes had a significantly higher WHR in comparison to NDM in both females (0.89 vs. 0.83) and males (0.97 vs. 0.92), and these observations are comparable to US diabetic populations (Li et al. 2010).

Socio-demographic characteristics varied significantly across diabetes groups in both females and males. Interestingly, the marriage rate amongst females and males with prevalent diabetes was the highest (77.2%, 92.7% respectively). On the other hand, the highest prevalence of being single was amongst non-diabetics (32.4% in females and 30.3% in males). Reports on marital status were significantly different across groups. In

contrast to the observations of this study, Western studies such as the Whitehall II study have found no association between marital status and diabetes (Kumari et al. 2004), whilst in the US marriage was associated with a higher diabetes prevalence amongst women (Beckles and Thompson-Reid 2001). There are no previous studies on marital status and the prevalence of diabetes in Saudi Arabia, however, local observational studies have shown a positive association between marriage and diabetes risk factors (Al-Nozha et al. 2007, Al-Baghli et al. 2008). In other areas in the Middle East such as Oman an association between marriage and risk of diabetes in 7179 adults has been reported (Al-Moosa et al. 2006), similar observations were reported in Iranian adults (Rahmanian et al.), whilst married Syrian adults have reported lower self-rated health (Albache et al. 2010).

There was no significant difference in consanguinity and consanguinity degree across diabetes groups. Females with T2DM reported the highest rate of consanguineous marriages (64.4%) and 57.3% married their first cousin. The overall prevalence of consanguineous marriages in Saudi Arabia is 56%, and marrying a first cousin is the most frequent amongst all marriages (33.6%) (Middle 2007). In Riyadh, around 40% of marriages are to a first degree cousin, and the prevalence of consanguineous marriages is similar to other Middle Eastern countries (El-Hazmi et al. 1995). It has been suggested that consanguinity may play a role in the prevalence of T2DM, but this has not previously been confirmed within the Saudi context (Elhadd et al. 2007, Al-Daghri et al. 2011). In Bahrain, there was no association between consanguinity and the prevalence of T2DM (Al-Mahroos and McKeigue 1998) which is in line with the findings in this thesis.

Numerous epidemiological studies have illustrated the association between sleep deprivation and several chronic conditions (Mallon et al. 2005, Gangwisch et al. 2006, Cappuccio et al. 2007, Stranges et al. 2008, Shankar et al. 2010, Stranges et al. 2012) and diabetes (Mallon et al. 2005, Yaggi et al. 2006, Cappuccio et al. 2010). The mean number of sleeping hours in the overall sample was 7.69 hours, and males reported significantly ($p = 0.005$) less sleeping hours (7.62) in comparison to females (7.80). The sex difference is in line with previous Saudi observations (Young et al. 1993), and in Chinese populations (Li et al. 2002). Participants with diabetes slept significantly less time than non-diabetics. Females with diabetes had higher reports of disrupted sleeping patterns (51.4%) in comparison to other groups. There is a lack of evidence on the association between sleep duration and quality and diabetes in Saudi. Shorter sleep duration has been associated with T2DM across several populations, mostly from developed countries (Yaggi et al. 2006, Cappuccio et al. 2010).

The overall prevalence of obesity in this project was 41.2% (47.7% in females and 35.0% in males), which was significantly higher amongst diabetics (64.5% in females, 41.4% in males). WC, WHR, and SAD were high in the overall sample, and significantly higher amongst participants with T2DM. In the overall sample, all anthropometric measures were significantly associated with T2DM. The associations remained significant after adjustment for potential confounders. In the overall sample, the highest association was observed for WC (OR 2.41, 95% CI, 1.69-3.44), followed by BMI (OR 2.08, 95% CI 1.4-3.0), then WHR (OR 1.84, 95% CI, 1.28-2.65), and finally SAD (OR 1.71, 95% CI, 1.24-2.54). Observational studies from neighbouring countries have reported similar associations between T2DM and different anthropometric measures. In the Gulf region, higher BMI (≥ 30 kg/m²) was significantly associated with T2DM in Kuwaiti adults (OR 1.46, 95% CI, 1.04-2.04) (Abdella et al.

1998). In the Middle Eastern region, Iran specifically, various anthropometric measures were investigated, such as WC (Bozorgmanesh et al. 2011), BMI (Sadeghi et al. 2007, Harati et al. 2009) and WHR (Sadeghi et al. 2007, Hadaegh et al. 2009); all showed statistically significant associations with T2DM. However, some other Middle Eastern studies have found that WC may be the strongest predictor of T2DM (Al-Asfoor et al. 1999, Onat et al. 2006, Hadaegh et al. 2007), whilst others suggest that WHR is a stronger predictor of T2DM (Satman et al. 2002, Mansour and Al-Jazairi 2007, Mansour and Al-Jazairi 2007). Nevertheless, the evidence originates from few countries in the Middle East, mainly Iran, and there is a general lack of Saudi observational studies.

The sex specific associations between anthropometric measures and T2DM were explored in the current study. The results showed that BMI ($\geq 30 \text{ kg/m}^2$) remained significantly associated with T2DM in females in the fully adjusted model (OR 3.39, 95% CI, 1.5-7.6) whilst this association attenuated in males. The prevalence of obesity was significantly higher in females in comparison to males which may explain this strong observation. BMI has also been found to be significantly associated with T2DM in Iranian women, and WC showed a significant association with T2DM (OR 3.1, 95% CI, 1.1-8.3, $p = 0.04$) (Hadaegh et al. 2009). The reported association may be driven by other covariates (socio-demographics, lifestyle, and female risk factors) which were not adjusted for in the Iranian study (Hadaegh et al. 2009).

A recent cross-sectional study which included 4989 Iranian females, aged ≥ 20 years, has reported a significant association between BMI and the prevalence of diabetes (Bozorgmanesh et al. 2010). The Turkish Diabetes Epidemiology Study reported a significant association between BMI, WHR and diabetes in women aged ≥ 20 years

(Satman et al. 2002). The results of the current study are similar to international populations. For example, BMI was strongly associated with diabetes in US women (Weinstein et al. 2004). In Australian adults, the age-adjusted association between BMI and diabetes was stronger in females in comparison to males (Dalton et al. 2003). In another investigation from the Nurses' Health Study in the US, overweight and obesity were the most important predictors of diabetes in adult women (Hu et al. 2001).

International studies have found that both BMI and WC were similar predictors for T2DM in males (Tulloch-Reid et al. 2003, Wang et al. 2005). However, this may not be the case in Saudi men, where central adiposity measures remained significantly associated with T2DM whilst the association attenuated for BMI. In males, WC, WHR, and SAD were all similarly associated with diabetes in the fully adjusted model. Neighbouring countries report conflicting evidence. For example, BMI has been significantly associated with diabetes prevalence in Iranian men, whilst WHR showed no significant association (Bozorgmanesh et al. 2010). On the other hand, both BMI and WHR were significantly associated with diabetes in Turkish men (Satman et al. 2002), whilst in Bahraini adults, central adiposity indicated by WC was strongly associated with T2DM (Al-Mahroos and McKeigue 1998). The results of this study are similar to Korean populations, where WC was associated with T2DM in men (Paek and Chun 2010). In the San Antonio Heart Study, WC was the best predictor of T2DM compared with other measures in 25–64 year old Mexican Americans (Wei et al. 1997). Similarly, the Atherosclerosis Risk in Communities (ARIC) cohort found that WC was a strong predictor for diabetes in African American and white adults (Stevens et al. 2001), whilst in Chinese populations both general obesity and central adiposity were similarly associated with diabetes (Jia et al. 2011).

In the overall sample, the results suggest that WC, a measure of central adiposity, is a much stronger correlate of diabetes than BMI, a measure of relative weight in this study. A direct and statistically significant association between the age-sex adjusted OR for diabetes and WC persisted in the two highest BMI categories. However, this association was not significant between BMI and diabetes across tertiles of WC. Researchers have previously found that abdominal fat localization often indicated by waist measure was more important than total body fat in predicting T2DM (Chan et al. 1994, Wei et al. 1997, Okosun et al. 1998). These findings seem to be applicable to Saudi populations, especially men, whilst relative weight seems to play a stronger role in Saudi women.

The calibration of the FFQ included 98 participants, an internal sub-sample of the original cohort. The crude correlation coefficients of the FFQ in this study ranged from 0.302 to 0.619, and these correlations are comparable to other food based validation studies of dietary questionnaires (Salvini et al. 1989, Bogers et al. 2004, Kobayashi et al. 2011, Barbieri et al. 2014). Validation of the FFQ has been conducted in Middle Eastern countries, such as Jordan (Dehghan et al. 2009) Iran (Mirmiran et al. 2010) and Kuwait (Dehghan et al. 2009). However, these studies were micro and macronutrient based validation studies. Therefore, it is not possible to compare the findings of this study to Middle Eastern studies. The correlation coefficient decreased after adjustment for energy intake in this study. The decreased energy adjusted correlations have been reported in previous validation studies (Munger et al. 1992, Riley and Blizzard 1995, Slater et al. 2003). It has been suggested that correlation coefficients decrease after energy adjustment because the variability of nutrient is dependent on measurement error, within- and between- person variance, of overestimation and underestimation (Willett 1998).

Measurement error can be corrected by a minimum of two replicates of the reference tool (Carroll et al. 1997), as was carried out in this study. The energy adjusted correlations improved after correction for measurement error. Correlation coefficients (mean $r = 0.63$) in our study are comparable to the mean correlations in the study by Franceschi et al. (mean $r = 0.67$) (Franceschi et al. 1993) and slightly higher than those found in the study by Barbieri et al. (mean $r = 0.41$) (Barbieri et al. 2014). The variance ratio of within- to between- person variance was greater than one for most foods. High variance ratio has been previously reported for nutrient and food intake (Beaton et al. 1979, Beaton et al. 1983, Feskanich et al. 1993, Slater et al. 2003). The lowest variance ratio was observed for dates and coffee which are staple dietary items in the Saudi diet (Alsaif et al. 2007). For dates and coffee, within person variance was lower than between person variance, which suggests that participants consumption was not affected by day-to day intake variation (Willett 1998). Overall, the FFQ was in agreement with the mean of the two 24-hour recalls for the food/beverages examined in this study.

The associations between selected food/beverages and T2DM was examined in a sub-sample ($n = 1867$) of the original cohort of this study ($n = 2631$). In this study, an interesting observation was found between date consumption and T2DM. Date intake was higher among non-diabetics in comparison to diabetics. Specifically, males with no prevalent diabetes reported significantly higher intakes of dates in comparison to diabetics. In the overall sample, reports on higher consumption of dates (servings/day) showed a significantly inverse association with diabetes. This association remained statistically significant after adjustment for covariates. The sex-stratified analysis showed an inverse association between date consumption and diabetes in both sexes. However, this association remained significant in males but not in females, likely as

result of limited statistical power in subgroup analyses. The association between date intake and T2DM has not been previously explored. However, studies examining date intake in relation to diabetes risk factors have reported a favourable association (Alsaif et al. 2007, Al-Rethaiaa et al. 2010). In a cross sectional study of 357 Saudi students aged 18-24, daily date intake was reported by 36.1% of participants. Frequent date consumption was inversely associated with visceral fat levels (Al-Rethaiaa et al. 2010). Animal feeding studies have found that date consumption significantly reduce lipid levels (Al-Orf 1992, Alsaif et al. 2007), whilst agricultural studies have reported the potential antioxidant property of dates (Vayalil 2002, Al-Farsi et al. 2005, Allaith 2008, Biglari et al. 2008, Hasan et al. 2010).

Khalas was reported as the type of dates consumed by the majority of participants in this study. The glycaemic index of Khalas dates was tested in 19 Saudi participants, the glycaemic index was 57.7 (Ahmed et al. 1991) suggesting that dates did not have a high glycaemic index (Jenkins et al. 1981). It has been reported that dates have a low glycaemic index, ranging from 35.5-47.2, which is lower than apples, oranges and bananas (Miller et al. 2002, Miller et al. 2003). The glycaemic index of five different dates was tested in 13 adults with no diabetes and 10 adults with diabetes. The findings showed no significant differences in the glycaemic response between diabetics and non-diabetics. The mean glycaemic index ranged from 43.8-53.0 in adults with diabetes further suggesting that dates have a low glycaemic index (Alkaabi et al. 2011). It has been well established that low glycaemic index dietary intake is associated with a lower diabetes risk (Willett et al. 2002, Hodge et al. 2004). Therefore, it is biologically plausible that dates may have a favourable effect on T2DM risk.

The association between nutritional biomarker, vitamin D and selenium, were examined in a random sub-sample ($n = 567$) of this projects original cohort ($n = 2631$). The results showed that participants had lower vitamin D levels (27.16 nmol/l) in comparison to Qatar (mean levels 29.25 nmol/l) (Mahdy et al. 2010), Iran (mean levels 32.48 nmol/l) (Hashemipour et al. 2006), France (mean levels 61 nmol/l) (Chapuy et al. 1997) and US (60 nmol/l) (Ginde et al. 2009). The results showed that higher education levels decreased across tertiles of vitamin D. Saudis with higher education are more likely to engage in indoor professions which decrease sun exposure. In Qatar, the majority of health care professionals with low vitamin D levels reported less time spent in the sun and more time spent indoors (Mahdy et al. 2010). However, Western studies have shown that higher education is associated with increased vitamin D levels (Holick et al. 2005, Kilkinen et al. 2009).

Previous studies have shown that vitamin D levels are lower in diabetics in comparison to non-diabetics (Scragg et al. 1995, Yoho et al. 2009), however, this may not be the case within the Saudi context. The results showed that non-diabetics had lower levels of 25 (OH) D in comparison to adults with glucose abnormalities (25.29 vs. 28.18 nmol/l respectively). This difference has been reported in a previous observational study conducted in Saudi Arabia. In 177 non diabetic Saudi adults the mean levels of vitamin D were lower in comparison to 164 T2DM adults (17.9 nmol/l vs. 26.9 nmol/l) (AL-Daghri et al. 2010). However, the study included participants with diagnosed diabetes. In Saudi Arabia, multivitamin supplementation is part of the treatment plan of T2DM, and this may explain the higher levels observed in T2DM participants (AL-Daghri et al. 2010).

Females with T2DM had significantly higher vitamin D levels. A possible explanation is the strong association observed between vitamin D levels and age in this study which was stronger amongst females. Participants with T2DM are significantly older than non-diabetics, and metabolic clearance of 25(OH)D declines with age because of a decline in kidney function (Vieth et al. 2003). Nevertheless, these observations are in agreement with other reports on vitamin D levels in older adults. In 1210 Iranian adults, higher vitamin D levels were observed in older adults than in younger Iranians (Hashemipour et al. 2004). Other international observations have also found that vitamin D levels are not lower in older individuals (Harris et al. 2000, Tangpricha et al. 2002, Vieth et al. 2003). The levels of vitamin D were higher amongst older US adults in comparison to younger adults (Tangpricha et al. 2002). In a Canadian study, Veith *et al.* found that vitamin D levels in 1741 participants were not lower in older participants (Vieth et al. 2003). In addition to the significant correlation observed between age and vitamin D levels, osteoporosis therapy may also explain this difference, because pharmacological treatment for this condition may boost vitamin D status amongst women (Sambrook et al. 2002). The prevalence of osteoporosis amongst Saudi females is extremely high and ranges from 50-70% (Sadat-Ali et al. 2004). Osteoporosis was not assessed in the original survey (2009), therefore, osteoporosis therapy was not controlled for in the analysis.

On the other hand, Saudi adults should also be considered as a selenium-replete population (mean levels 104.35 ng/ml), similar to countries with high selenium status such as the Lebanon (142 ng/ml) (Obeid et al. 2008), US (125.7 ng/ml) (Bleys et al. 2008), Canada (115 ng/ml) (Gibson et al. 1985), and Japan (107 ng/ml) (Imai et al. 1990). There was no sex-specific difference in Se concentrations (104.59 ng/ml in both females and males). Some observational studies have reported a sex-specific difference

in Se concentrations, where males had higher levels than females (Kafai and Ganji 2003, Laclaustra et al. 2009). Studies from the Middle East have reported controversial observations on the difference in Se status in males and females. In Kuwaiti adults there was no significant difference in Se levels between males (87.4 µg/l) and females (87.6 µg/l) (Al-Sayer et al. 2000). On the other hand, Iranian females (93.9 µg/l) had significantly lower selenium levels in comparison to Iranian males (102.2 µg/l). Nevertheless, Saudi females have higher selenium concentrations in comparison to Kuwaiti (Al-Sayer et al. 2000), Iranian (Safaralizadeh et al. 2005), and Turkish (Coskun et al. 2013) females. In 398 Lebanese adults, Se concentrations were higher in males (151.2 ng/ml) in comparison to females (135 ng/ml) (Obeid et al. 2008).

In this study, both females and males with diabetes had the highest levels of serum Se. Diabetes markers (FPG, and fasting insulin) and the prevalence of diabetes increased across Se tertiles, however this did not reach statistical significance. International evidence has suggested an association between high Se status and diabetes (Bleys et al. 2007, Stranges et al. 2007, Laclaustra et al. 2009). One study in Saudi Arabia examined urinary Se in 340 adults (diabetics and non-diabetics). Although there was no difference in Se levels between diabetics and non-diabetics, urinary Se was significantly associated with HbA1c levels in Saudi adults (El-Yazigi and Legayada 1996). In 398 Lebanese adults, serum Se levels were significantly associated with glucose levels (Obeid et al. 2008).

A significant association between fasting insulin and serum Se was observed in the overall sample (0.111, $p = 0.011$) and in males (0.134, $p = 0.034$). International studies have reported an association between insulin resistance and high Se levels (Chen et al. 2003, Stranges et al. 2007). Mice with elevated Glutathione peroxidase 1, the most

abundant selenoprotein in mammals, developed insulin resistance (McClung et al. 2004). Furthermore, Chen *et al.* reported an association between insulin resistance and glutathione peroxidase activity in 408 non-diabetic women during pregnancy (Chen et al. 2003).

Finally, cultural barriers to healthy eating in participants with and without T2DM were explored in this project. The sample was a subsample ($n = 108$) of this project's original cohort ($n = 2631$). The findings of the current study showed that Saudi females were aware of their weight problem, preferred to lose weight and believed that healthy eating will reduce their body weight. This is in line with a recent study by Al Musaiger *et al.* where 65% of Arab females preferred a thinner body size (Musaiger 2013). The main barriers amongst females were resistance to change and lack of willpower, they thought that they did not need to or were not ready for dietary modification. Lack of willpower was also perceived as a barrier in 301 Saudi females, where over 80% of females reported lack of willpower as a barrier to healthy eating (AlQuaiz and Tayel 2009).

Males with no diabetes associated healthy eating with better health in general; healthy eating mattered to them because they were getting older. Gough et al. reported a similar observation amongst males in the UK where age was a factor when considering dietary changes (Gough and Conner 2006). Males with diabetes perceived health as precious and irreplaceable; the main barrier was lack of need which was associated with a positive attitude towards their current health condition. Saudi nationals practice Islam as a religion, and they have a strong and unquestionable faith in God. Saudis believe that health, disease and death is God's will, therefore they believe that illness is a predestination from God and it will erase a person's sins (Aldossary et al. 2008).

Lack of dietary knowledge was observed in the overall sample. The quantitative data showed that lack of knowledge was higher amongst males with diabetes (19.4%) in comparison to non-diabetics (5.3%). The qualitative data showed that participants struggled to answer questions or expressed lack of knowledge in different forms such as misconceptions and food confusion. Females thought that healthy eating included only fruits and vegetables. Participants, who had previously consulted a dietician, thought that dry food and bitter food were good for diabetes. The same reported misconceptions in this study have been reported in a previous study which assessed dietary misconceptions in 1039 Saudi diabetics. The study showed that over 53% of diabetics thought that bitter food and dried bread is good for diabetes (Al-Saeedi et al. 2002). These results are in line with the current study where 65.7% of participants thought that bitter food will reduce blood sugar and 43.5% thought that toasted bread contains less sugar. Dietary confusion was clear amongst participants, for instance cheese and olive oil were reported as carbohydrates. Lack of dietary knowledge was previously reported in 151 Saudi females (Bakhotmah 2012). Only 38.9% of females were able to correctly list foods in food groups (Bakhotmah 2012).

Lack of social support was a barrier to 47% of males in this study. In another study conducted in 144 Saudi males, lack of social support, which includes family and social pressure, was a barrier for 69.3% of participants (AlQuaiz and Tayel 2009). Males complained about the pressure/insistence to over eat at social occasions, if they had to cave into this pressure for social occasions then why bother to eat healthily at other times. Hospitality is a strong feature of the Saudi culture, it is not linked to social class or wealth in Saudi Arabia. Frequent social occasions such as family gatherings and weddings require displays of hospitality which mainly include large amounts of food.

Hospitality in Saudi Arabia includes extensive greetings, insistence, emphasis, and assistance to join their occasion (Ellen 1997).

Reliance was reported by the majority of participants and especially by males. The findings indicated that participants thought that illness or health is a predestination from God. Participants believed that it is not their responsibility to take action and they relied on the health care system to identify their health needs and manage their health issues. Reliance may be a consequence of lack of patient awareness, involvement and effective communication between health care providers and patients (Mobeireek et al. 1996, Saeed et al. 2001). It has been reported that primary health care attendees in Saudi Arabia were not fully aware of the health educators role (Asiri et al. 2013). Some participants were not aware of the available services whilst others did not know how to access this service.

Overall, participants were dissatisfied with the available lifestyle modification service. Participants found it very difficult to consult a health educator because of limitations in the health system (physicians referral, lengthy process, lack of staff). They expressed in body language, voice tone and verbal response their anger and dissatisfaction with the health services. Primary health care centres in Riyadh have a shortage of health education staff (Asiri et al. 2013) and a physician's referral is required to access this service (Saeed et al. 2001).

12.4. Implications for policy

The findings of this study are expected to be valuable in diabetes health policy formulation and action in Saudi Arabia. There is a need to raise the awareness and

understanding within policy circles (e.g., Saudi Ministry of Health) about the correlates of diabetes in Saudi adults, so that appropriate health policy can be executed. Policy makers need to know that cultural-specific diabetes awareness programs are extremely important to engage the Saudi population in lifestyle modification.

Based on the fact that waist circumference was independently associated with T2DM, waist circumference measurements can be considered in Saudi settings. Waist circumference measurements would help to identify adults at risk of developing type 2 diabetes as early detection will enable early preventive intervention measures to be taken. Waist circumference is cheap and easy to measure, and does not involve further complex calculations, and thus may be suitable for primary health care settings. Culturally specific cut-off points for anthropometric measures for diabetes risk should be developed to accurately identify people at risk. Diabetes and nutritional public awareness campaigns are essential for the Saudi population. Currently, the Ministry of Health in Saudi Arabia runs eight national campaigns, none of which covers diabetes or dietary awareness (MOH 2012). Most importantly, such national campaigns should be informed by local studies to develop culturally specific awareness and intervention programs.

The Ministry of Health in Saudi Arabia should also increase the public's awareness about the readily available health services, especially health education and lifestyle modification services. Current dietetic practice should be evaluated and educational material, using lay language, should be available. The findings of this thesis have highlighted the dissatisfaction of Saudi individuals with the available health services, therefore, the process of accessing such services and available facilities should be evaluated to implement change and improve health services. Collaboration between the

Ministry of Health and religious authorities could be useful to raise health awareness in religious settings (e.g. mosques) to target large numbers of the public.

12.5. Implications for practice

The findings of this study will be valuable in designing future health-care strategies in Saudi Arabia to reduce the burden of diabetes. Health care professionals should be prepared to play a key role in the prevention of diabetes and its related risk factors in order to prevent future burden.

Additional anthropometric measurement, such as waist circumference, of adults could be incorporated as part of the routine physical examination in a hospital or primary health care setting for early detection of diabetes risk factors. Health care professionals should increase adults' awareness about vitamin D insufficiency and provide culturally appropriate educational resources to increase vitamin D levels. For instance, the cultural dress code prevents Saudi people from direct sun exposure, therefore sun exposure could be carried out in the privacy of their own home. Health care professionals should improve their interpersonal skills to improve communication with patients. For instance, motivational interviewing could be adopted to address patient specific needs and help in motivating and initiating behavioral change (Rubak et al. 2005). Most importantly, health care educators should use lay language when delivering health messages to the general public.

12.6. Implications for research

The findings of this study showed that T2DM is an important research priority and highlighted the urgent need of T2DM studies in Saudi Arabia. Specifically, it is extremely important to identify cultural-specific risk factors associated with T2DM to develop culturally tailored diabetes awareness campaigns which are currently lacking in Saudi Arabia. This study showed that future research on dietary factors and the prevalence of diabetes in Saudi adults should include:

- 1) Large representative national surveys with standardised and robust methods to further assess the prevalence of diabetes in Saudi adults.
- 2) Epidemiological surveys with standardised methods that can be used to develop Saudi specific cut-off points for anthropometric measures. There is a need for standardised population-specific anthropometric measures due to biological differences between populations. This is important to quantify the extent of the problem and have cultural specific cut-off points to better assess diabetes risk.
- 3) Large representative national surveys with standardised and robust methods to further assess the prevalence of vitamin D deficiency in Saudi adults. Such surveys should incorporate the assessment of cultural factors that may be associated with low vitamin D levels, such as clothing information, sun exposure, working environment, dietary intake, supplements intake, and skin color.
- 4) The development of a large Saudi specific nutritional database that could be used in large nutritional epidemiological studies.
- 5) The assessment of the glycaemic index and nutritional properties of different varieties of dates which are available in Saudi Arabia to better understand the biological effect of dates on diabetes.

- 6) The development and validation of a food frequency questionnaire to assess dietary intake in large nutritional epidemiological studies.
- 7) Large representative national nutritional surveys with valid nutritional tools and robust methods to quantify dietary intake of Saudi adults.
- 8) Studies evaluating current dietary education practices in Saudi health settings to better understand the health messages delivered to the public.
- 9) Qualitative health research, with in depth interviews, to better understand cultural specific health issues and to inform current and future quantitative research.
- 10) Longitudinal studies with standardised protocols to investigate future trends in the relationship between diabetes prevalence and social, environmental, behavioural and dietary factors. This will be significant in evaluating the importance of these factors on diabetes prevalence in Saudi adults.
- 11) Collaborative work between Saudi Arabia and Middle Eastern countries to better understand dietary differences across different countries in the region. This will be important to exchange knowledge and evaluate the role of different dietary factors on diabetes prevalence in the Middle Eastern region.

12.7. Conclusion

The high prevalence of diabetes increases the burden of non-communicable diseases in Saudi Arabia, and prevention of chronic conditions is a priority. This study suggests that culturally specific factors may play an important role in the diabetes epidemic in Saudi Arabia. This study has identified major gaps in dietary literature in the Middle Eastern region in general and Saudi Arabia specifically. The Saudi evidence on diabetes and potential risk factors mainly originates from observational studies of poor

methodology, and well-designed dietary studies are lacking. Therefore, the available literature is not sufficient to identify dietary risk factors associated with the risk of T2DM in Saudi populations.

This study provides further evidence showing that anthropometric measures of adiposity are associated with T2DM prevalence in Saudi settings. It also provides new evidence on the association between waist circumference and T2DM prevalence in Saudi adults. This study was the first to validate a food frequency questionnaire in Saudi Arabia and has confirmed the importance of energy adjustment and measurement error when reporting dietary intake. This is the first study which examines the association between food/beverage items and the prevalence of diabetes in Saudi Arabia. Interestingly, date intakes showed a favourable association with the prevalence of T2DM.

This study confirms that vitamin D insufficiency is widespread in Saudi adults, whereas Saudis should be considered as a selenium-replete population for their selenium status. Vitamin D levels were evaluated for the first time in Saudi adults who were unaware of their diabetes. The findings showed that females with diabetes had significantly higher levels of vitamin D in comparison to non-diabetics. However, these findings should be interpreted with caution due to potential residual confounding. The findings of this study showed that serum selenium was associated with diabetes markers but not diabetes prevalence, and that high selenium levels may be associated with lipid abnormalities in Saudi adults.

This study provides interesting insights into culturally specific barriers associated with eating habits in Saudi individuals. The findings found that the social pressure and lack of support negatively influence healthy eating habits in Saudi adults. The findings also

suggest that the general public may not properly understand dietary awareness messages delivered by health care professionals. Lack of communication between health authorities and the general public may play a role in Saudis resistance to adopt healthy lifestyle practices. There is an urgent need to develop culturally tailored awareness campaigns at a national level, specifically to prevent T2DM and improve nutritional knowledge.

12.8. Scientific outputs

Chapter 5:

Al-Khudairy, L., Stranges, S., Kumar, S., Al-Daghri, N. and Rees, K. (2013). Dietary Factors and Type 2 Diabetes in the Middle East: What Is the Evidence for an Association?—A Systematic Review. *Nutrients*, 5(10):3871-3897.

Chapter 8:

Al-Khudairy, L., Rees, K., Kumar, S., Al-Daghri, N., Al-Attas, O., Alkail, M., Alkharfy, K. and Stranges, S. Central adiposity as a driver of the type 2 diabetes epidemic in Saudi people. Submitted to: 58th SSM Annual Scientific Meeting, Keble College, University of Oxford, Oxford, United Kingdom, September 10-12, 2014.

Chapter 11:

Al-Khudairy, L., Stranges, S., Kumar, S., Al-Daghri, N., Al-Attas, O., Alokail, M., Alkharfy, K. and Rees, K. Cultural barriers to healthy eating in Saudi adults with and without type 2 diabetes (T2D). Submitted to: 58th SSM Annual Scientific Meeting, Keble College, University of Oxford, Oxford, United Kingdom, September 10-12, 2014.

Awards:

Highly commended research poster presentation. Cultural barriers to healthy eating in Saudi adults. Warwick Medical School Annual meeting (2012), Warwick Medical School, University of Warwick, Coventry, United Kingdom.

Best oral presentation symposium prize. Nutrition and type 2 diabetes in Saudi Arabia. Postgraduate Student Symposium (2013), Warwick Medical School, University of Warwick, Coventry, United Kingdom.

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Appendix 1: The Biomarkers Screening Survey (2009) questionnaire

Kingdom Of Saudi Arabia Ministry Of Higher Education King Saud University Vice Rectorate for K. E. T. T. College of Science Research Center For Biomarkers		المملكة العربية السعودية وزارة التعليم العالي جامعة الملك سعود وكالة الجامعة للتبادل المعرفي ونقل التقنية كلية العلوم مركز أبحاث المؤشرات الحيوية
National Screening For Biomarkers المسح الوطني للمؤشرات الحيوية		
Serial No. : _____		Date: ____ / ____ / 2009
National ID: - - - - - رقم الهوية		Name: _____ الاسم
Sex الجنس: () M ذكر () F أنثى		Age : _____ العمر
Birth Date ____ / ____ / تاريخ الولادة		Place : _____ المكان Phone : _____ التلغون
الحالة الاجتماعية		
<input type="checkbox"/> أعزب Marital status Single	<input type="checkbox"/> متزوج Married	<input type="checkbox"/> مطلق Divorced
<input type="checkbox"/> أرمل Widowed	<input type="checkbox"/> طفل Child	
♦ If you married is your wife or husband your relative ؟ No / لا <input type="checkbox"/> Yes / نعم <input type="checkbox"/>		
♦ Relative Degree 2 nd degree / درجة ثانية <input type="checkbox"/> 1 st degree / درجة أولى <input type="checkbox"/> درجة القرابة درجة أولى (من جهة العم أو العممة ، أو الخال أو الخالة) ما عدا ذلك درجة ثانية		
الحالة الاقتصادية والتعليمية Socio-economic status		
Annual Income: الدخل السنوي <input type="checkbox"/> ليس له دخل <input type="checkbox"/> أقل من ٥٠٠٠ ريال <input type="checkbox"/> ١٠٠٠٠ - ٥٠٠٠ ريال <input type="checkbox"/> ٢٠٠٠٠ - ١٠٠٠٠ ريال <input type="checkbox"/> أكثر من ٢٠٠٠٠ ريال	Job: العمل Government <input type="checkbox"/> حكومي Private <input type="checkbox"/> خاص Retired <input type="checkbox"/> متقاعد No work <input type="checkbox"/> بدون عمل	Education: المستوى التعليمي uneducated <input type="checkbox"/> أمي Pre. college <input type="checkbox"/> متوسط College <input type="checkbox"/> جامعي High Edu. <input type="checkbox"/> عالي
Family history التاريخ العائلي :		
سكري أقارب من الدرجة الأولى Diabetes 1 st degree <input type="checkbox"/> أب <input type="checkbox"/> أم <input type="checkbox"/> أخوه <input type="checkbox"/> أطفال	سكري أقارب من الدرجة الثانية Diabetes 2 nd degree <input type="checkbox"/> جد <input type="checkbox"/> عم <input type="checkbox"/> خال <input type="checkbox"/> أحفاد	ارتفاع ضغط الدم Hyper tension <input type="checkbox"/>
ارتفاع الدهون <input type="checkbox"/> Hyperlipidemia	سمنة <input type="checkbox"/> Obesity	سرطان <input type="checkbox"/> Cancer
<input type="checkbox"/> Others أخرى : _____		
Subject Medical history التاريخ المرضي للفرد : () CHD () HTN () Dyslipidemia () Diabetes () Asthma () Cancer () Liver Disease () Kidney Disease Others: _____ (حدد)		
Smoking التدخين (adults):		
() Smoker مدخن () Ex-Smoker مدخن سابق () Never smoked لم يدخن إطلاقاً	شيشة Sheshah () # of packs/day _____ - Duration (years) _____ - Years quitted _____	عدد علب السجائر أو الشيشة في اليوم المدة بالسنوات سنوات الإقلاع
للاستفسار : ت : ٤٦٥٩٣٩ ، فاكس : ٤٦٥٩٣١ - جوال : ٥٣٠٧٨٧١٢١ - ndaghri@ksu.edu.sa		

Physical activity النشاط البدني (adults): () Yes نعم () No لا

If yes, please answer the following questions إذا نعم اجب علي الأسئلة التالية:

Frequency of physical activity معدل النشاط البدني:

يومياً ☐ ٣ - ٤ مرات أسبوعياً ☐ ١ - ٢ مرات أسبوعياً ☐ بعض المرات شهرياً ☐ مرة في الشهر ☐
Daily 3 - 4 times a week 1-2 times a week Few times a month once a month

النشاط البدني Type of activity	Frequency (minutes)			
	<10	10-20	20-30	30>
Hard physical exercise (e.g. Running, bicycling, ...) نشاط بدني قوي الركض وركوب الدراجة				
High physical exercise (Tennis, Handball, ...) نشاط بدني عالي التنس وكرة اليد				
Middle (1) physical exercise (Volleyball walking, house cleaning, ...) نشاط بدني متوسط (١) المشي السريع وتنظيف البيت				
Middle (2) physical exercise (Table tennis, housekeeping, ...) نشاط بدني متوسط (٢) كرة طاولة ، ترتيب البيت				
Low physical exercise (Normal walking, ironing, dish washing, ...) نشاط بدني منخفض (مشي ، كوي الملابس ، غسيل الصحون				

No. of sleeping hours () عدد ساعات النوم () متقطعة () متصلة

أسئلة للسيدات فقط For Female Subjects Only

Age at Menarche _____ العمر عند ظهور الدورة الشهرية :

Years of Menopause (For menopausal only): _____ فترة انقطاع الدورة :

Are you pregnant ؟ هل انتي حامل ؟ [] Yes نعم [] No لا [] week في أي أسبوع

Age at 1st pregnancy _____ العمر عند الحمل الأول :

History of Hormone Replacement Therapy (HRT):

استخدام معوضات الهرمونات لسن انقطاع الدورة [] Yes نعم [] No لا

History of GDM [] Yes نعم [] No لا مشاكل سكر الحمل

History of mammogram [] Yes نعم [] No لا أشعة للثدي

History of Breast Lesions [] Yes نعم [] No لا إصابات بالثدي

(Specify) _____

History of Breast Surgery [] Yes نعم [] No لا عملية جراحية سابقة لإزالة الثدي

Date / / التاريخ

Breast Examination فحص الثدي

[] Never إطلاقاً [] Occasional أحياناً [] Regular بشكل منتظم

أسئلة للرجال فقط For Male Subjects Only

History of prostate Cancer [] Yes Date / / [] No لا ورم البروستاتا

History of Surgery [] Yes Date / / [] No لا عملية جراحية لإزالة البروستات سابقة

Digital Rectal Exam فحص البروستات شرجياً

[] Never إطلاقاً [] Occasional أحياناً [] بشكل منتظم

Examination الفحص الطبي :

الوزن Weight (kg) الطول Height (cm) الخصر Waist (cm) الأرداف Hip (cm) SAD (cm)

Blood Pressure ضغط الدم : /

Type of Diabetes نوع السكري :

النوع الأول النوع الثاني ما قبل السكري سكر الحمل
☐ ☐ ☐ ☐
 Type 1 Diabetes Type 2 Diabetes IGT GDM
☐ Other types أنواع أخرى Duration مدة المرض : _____ years

Complications المضاعفات :

☐ DKA إغماء ☐ Hypoglycemia هبوط السكر ☐ Neuropathy أمراض عصبية ☐ Retinopathy أمراض عيون
 _____ per year _____ per year
☐ Nephropathy أمراض كلوية ☐ Vasculopathy أمراض الجهاز الوعائي ☐ Laser عملية ليزر ☐ Foot ulcer قرحة القدم
☐ Dialysis غسيل كلوي ☐ Cataract ماء بيضاء ☐ IHD أمراض قلب ☐ CVA جلطات دماغية
☐ PVD أمراض الشرايين الطرفية

Handicap معاق :

☐ Blindness أعمى ☐ Amputation ممتور القدم أو اليد ☐ Stroke سكتة دماغية
☐ Dialysis غسيل كلوي ☐ Heart failure فشل قلبي ☐ Deafness أصم ☐ Muteness أبكم

Treating Physician الطبيب المعالج :

☐ General practitioner طبيب عام ☐ Internist أخصائي باطنية ☐ Endocrinologist استشاري سكري وغدد صماء

Admission for diabetes دخول للمستشفى بسبب السكري :

Number عدد المرات : _____

Duration المدة : _____

Others

حدد

List of Medications

(Place a check on all medications used by the subject)

Anti-diabetic Agents

- | | |
|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Insulin – insulin analogues Statins | <input type="checkbox"/> Amiodarone – Amiodarone, Cordarone |
| <input type="checkbox"/> Tolbutamide - Orinase | <input type="checkbox"/> Disopyramide – Rythmodan |
| <input type="checkbox"/> Tolazamide - Tolinase | <input type="checkbox"/> Flecainide acetate – Apo-Flecainide |
| <input type="checkbox"/> Chlorpropamide - Diabinese | <input type="checkbox"/> Mexiletine – Novo-Mexiletine |
| <input type="checkbox"/> Glipizide - Glucotrol | <input type="checkbox"/> Procainamide – Procan |
| <input type="checkbox"/> Glyburide – Micronase, Diabeta | <input type="checkbox"/> Propafenone – Rhythmol, Nu, Apo, Gen, PMS |
| <input type="checkbox"/> Glimepiride – Amaryl | <input type="checkbox"/> Digoxin |
| <input type="checkbox"/> Gliclazide - Diamicron | <input type="checkbox"/> Clonidine |
| <input type="checkbox"/> Repaglinide | <input type="checkbox"/> Methyldopa |
| <input type="checkbox"/> Acarbose | <input type="checkbox"/> Diazoxide |
| <input type="checkbox"/> Metformin – Repaglinide Thiazolidinediones | <input type="checkbox"/> Hydralazine |
| <input type="checkbox"/> Pioglitazone - Actos | <input type="checkbox"/> Isosorbide dinitrate |
| <input type="checkbox"/> Rivoglitazone | <input type="checkbox"/> Nitroglycerin |
| <input type="checkbox"/> Rosiglitazone – Avandia | <input type="checkbox"/> Prazosin, Terazosin, Dozazosin |
| <input type="checkbox"/> Troglitazone | <input type="checkbox"/> Atenolol, Acebutolol, Bisoprolol, Labetalol, Metoprolol, Nadolol, Oxprenolol, Pindolol, Propranolol, Sotalol, Timolol, |

Anti-Hyperlipidemics

- | | |
|-----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Atorvastatin – Lipitor, Torvast | <input type="checkbox"/> Amlodipine, Felodipine, Nifedipine |
| <input type="checkbox"/> Cerivastatin – Lipobay | <input type="checkbox"/> Diltiazem, Verapamil |
| <input type="checkbox"/> Fluvastatin – Lescol, Lescol XL | <input type="checkbox"/> Captopril, Benazepril, Enalapril, Cilazapril, Perindopril, Quinapril, Ramipril, Lisinopril |
| <input type="checkbox"/> Lovastatin – Mevacor, Altocor, Altoprev | <input type="checkbox"/> Candesartan, Irbesartan, Losartan, Telmisartan, Valsartan |
| <input type="checkbox"/> Mevastatin | <input type="checkbox"/> Spironolactone |
| <input type="checkbox"/> Pitavastatin – Livalo, Pitava | <input type="checkbox"/> Hydrochlorothiazide |
| <input type="checkbox"/> Pravastatin – Pravachol, Selektine, Lipostat | <input type="checkbox"/> Furosemide |
| <input type="checkbox"/> Rosuvastatin – Crestor | <input type="checkbox"/> pentoxyphylline |
| <input type="checkbox"/> Simvastatin – Zocor, Lipex | |
| <input type="checkbox"/> Simvastatin + Ezetimibe – Vytorin | |
| <input type="checkbox"/> Atorvastatin + Amlodipine – Caduet | |
| <input type="checkbox"/> Simvastatin + Niacin – Simcor | |
| <input type="checkbox"/> Cholestyramine | |
| <input type="checkbox"/> Colestipol | |
| <input type="checkbox"/> Benzafibrate, fenofibrate | |
| <input type="checkbox"/> Gemfibrozil | |

Cardiovascular drugs

- | | | |
|--------------------------------------|------------------------------------|----------------------------------|
| <input type="checkbox"/> Aspirin | <input type="checkbox"/> Warfarine | <input type="checkbox"/> Heparin |
| <input type="checkbox"/> Clopidogrel | | |

Others (Please specify)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

Appendix 2: The Biomarkers Screening Survey (2009) food frequency questionnaire

If you eat the food every day select No. 7

If you eat the food three days a week select No. 3

If you eat food once every two weeks or once a month select M

If you rarely eat food or never select N

1 2 3 4 5 6 7 M N

!

As you will be asked to determine the amount of food, please identify the quantity in weight (gram) or cup or spoon or number of pieces, e.g. quantity of milk (cup), and meat (gm), sugar (teaspoon).

Bread

Usually, how many times do you eat **white bread** (bakery)?

1 2 3 4 5 6 7 M N

How many pieces (1/4 loaf) eat during the day?

.....

Select the size of a loaf of bread? (Please choose the appropriate answer)

1. Large
2. Medium
3. Small

Usually, how many times do you eat **brown bread** (bakery)?

1 2 3 4 5 6 7 M N

How many pieces (1/4 loaf) eat during the day?

.....

Select the size of a loaf of bread? (Please choose the appropriate answer)

1. Large
2. Medium
3. Small

Usually, how many times do you eat the **white bread "Shami"**?

1 2 3 4 5 6 7 M N

How many pieces (1/4 loaf) eat during the day?

.....

Select the size of a loaf of bread? (Please choose the appropriate answer)

1. Large
2. Medium
3. Small

Usually, how many times do you eat **brown bread "Shami"**?

1 2 3 4 5 6 7 M N

How many pieces (1/4 loaf) eat during the day?

.....

Select the size of a loaf of bread? (Please choose the appropriate answer)

1. Large
2. Medium
3. Small

Usually, how many times do you eat **white toast slices**?

1 2 3 4 5 6 7 M N

How many slices you eat during a day?

.....

Select the size of Toast? (Please choose the appropriate answer)

1. Jumbo / large
2. Normal

Usually, how many times do you eat **brown toast slices**?

1 2 3 4 5 6 7 M N

How many slices you eat during a day?

.....

Select the size of Toast? (Please choose the appropriate answer)

1. Jumbo / large
2. Normal

How many times do you eat Samoli bread - Rounded (for Hamburger) - Tamis - tea cakes - corosan - pie per week?

1 2 3 4 5 6 7 M N

How many pieces you eat during the day?

.....

What other kinds of bread do you eat?

1. Samoli bread or Rounded (for Hamburger) white
2. Samoli bread or Rounded (for Hamburger) brown
3. Tamis white bread
4. Tamis brown bread
5. Tea Cakes
6. corosan
7. small pie
8. More than the type of this species

Usually, how many times do you eat Shaboura?

1 2 3 4 5 6 7 M N

What is the type of Shaboura?

1. Shaboura with sesame
2. wheat Shaboura
3. brown Shaboura
4. brown Shaboura with bran and cereals
5. brown Shaboura with cereals without bran
6. Shaboura with Mussels

What is the amount of shaboora eaten per occasion?

.....

Select the size of a piece of Shaboura? (Please choose the appropriate answer)

1. Large
2. Medium
3. Small

Usually, how many times do you eat jam / honey with the bread?

1 2 3 4 5 6 7 M N

Cereals for breakfast

Usually, how many times do you eat the following grains? (Specify quantity)

Corn Felix (corn chips)

1 2 3 4 5 6 7 M N Cup

Corn Felix with nuts or sugar or Coco Pops

1 2 3 4 5 6 7 M N Cup

Chicken meat: roasted, cooked, burger, shawrma

1 2 3 4 5 6 7 M N Cup

Special K or Rice Krispies

1 2 3 4 5 6 7 M N Cup

Muesli, with Fruit and fiber, Cheerios

1 2 3 4 5 6 7 M N Cup

Weetabix, Shredded wheat

1 2 3 4 5 6 7 M N Cup

Bran flakes, Wheat flakes or Sultana bran

1 2 3 4 5 6 7 M N Cup

Porridge or Ready Brek

1 2 3 4 5 6 7 M N Cup

All Bran

1 2 3 4 5 6 7 M N..... Cup

How many teaspoons of sugar / honey do you add to cereals?

How many times do you usually eat wheat bran? 1 2 3 4 5 6 7 M N

Meat

Usually, how many times do you eat the following meat and meat dishes? Specify quantity

Beef: roasted, steak, cooked pieces, burger, of lasagne

1 2 3 4 5 6 7 M N Grams

Sheep meat: grilled, cooked pieces, shawrma

1 2 3 4 5 6 7 M N Grams

Chicken meat: roasted, cooked pieces, burger, shawrma

1 2 3 4 5 6 7 M N Grams

Canned meat such as cold cuts

1 2 3 4 5 6 7 M N Grams

Sausages

1 2 3 4 5 6 7 M N Grams

What is the type of sausages used?

1. Cow
2. Turkey
3. Chicken

Meat pie, meat smbosa, mintoo, kebbah (prepared in the shop)

1 2 3 4 5 6 7 M N Grams

Meat pie, meat smbosa, mintoo, kebbah (prepared at home)

1 2 3 4 5 6 7 M N grams

Heart - kidney – liver

1 2 3 4 5 6 7 M N Grams

Are you eating fat meat with meat?

1. Yes
2. No

Fish

Usually, how many times do eat the following fish? (Specify quantity)

White fish (cod, grouper, shark)

1 2 3 4 5 6 7 M N Grams

Fish fingers

1 2 3 4 5 6 7 M N Grams

Fatty fish (salmon, sardine)

1 2 3 4 5 6 7 M N Grams

Canned fish (salmon, canned sardine)

1 2 3 4 5 6 7 M N Grams

Tuna, fresh or canned

1 2 3 4 5 6 7 M N Grams

Oyster, shrimp

1 2 3 4 5 6 7 M N Grams

Vegetables and other dishes

Usually, how many times you are eating the following items? please specify the quantity

Boiled or mashed potatoes

1 2 3 4 5 6 7 M N

Potato chips prepared in the shop

1 2 3 4 5 6 7 M N

Potato chips prepared at home

1 2 3 4 5 6 7 M N

Roasted Potato

1 2 3 4 5 6 7 M N Cup

Peas

1 2 3 4 5 6 7 M N Cup

Green vegetables, salad, or tomato

1 2 3 4 5 6 7 M N Cup
Carrots	
1 2 3 4 5 6 7 M N Cup
Sweet corn, turnip, white carrots	
1 2 3 4 5 6 7 M N Cup
Canned white beans	
1 2 3 4 5 6 7 M N Cup
Red beans	
1 2 3 4 5 6 7 M N Cup
Fava Beans	
1 2 3 4 5 6 7 M N Cup
Falafel	
1 2 3 4 5 6 7 M N Cup
Homos, lentils	
1 2 3 4 5 6 7 M N Cup
Onion (cooked / fresh)	
1 2 3 4 5 6 7 M N Cup/piece
Pasta / Noodles (With meat dressing - tomato dressing - or Lasagne)	
1 2 3 4 5 6 7 M N Cup
White rice	
1 2 3 4 5 6 7 M N Cup
Bolied rice	
1 2 3 4 5 6 7 M N Cup
Rice (Kabsa, Mendy, Bukhari)	
1 2 3 4 5 6 7 M N Cup
Greesh	
1 2 3 4 5 6 7 M N Cup
Harees	
1 2 3 4 5 6 7 M N Cup
Marasia	
1 2 3 4 5 6 7 M N Cup
Gursan, Markoq, Mtaziz	
1 2 3 4 5 6 7 M N Cup

Pizza

1 2 3 4 5 6 7 M N Cup

Vegetarian burger or vegetarian sausage

1 2 3 4 5 6 7 M N Cup/piece

Biscuits – cakes- deserts

Usually, how many times you are eating the following items? please specify the quantity

Biscuits or digestive biscuits

1 2 3 4 5 6 7 M N

Other types of local biscuits

1 2 3 4 5 6 7 M N

Chocolate: (Kit Kat, Twiks, Mars, Galaxy)

1 2 3 4 5 6 7 M N

Sweets like gum flavoured with fruit, mint, candy

1 2 3 4 5 6 7 M N

Snacks such as potato chips

1 2 3 4 5 6 7 M N

Nuts

1 2 3 4 5 6 7 M N

Ice cream, Mousse

1 2 3 4 5 6 7 M N

Yogurt (yogurt with cream/fruit)

1 2 3 4 5 6 7 M N

Fruit cake, sponge cake (prepared in shop)

1 2 3 4 5 6 7 M N

Fruit cake, sponge cake (prepared at home)

1 2 3 4 5 6 7 M N

Tart with fruit, doughnut (prepared in shop)

1 2 3 4 5 6 7 M N

Tart with fruit, doughnut (prepared at home)

1 2 3 4 5 6 7 M N

Arabic Sweets (Baqlavah, Basbosa)

1 2 3 4 5 6 7 M N

Muhala

1 2 3 4 5 6 7 M N

Hanneni

1 2 3 4 5 6 7 M N

Cream caramel, custard

1 2 3 4 5 6 7 M N

What kind of milk used in Cream caramel, custard?

1. Full-fat
2. Low fat
3. Skimmed

Fruits

How many times do you usually eat canned fruit (sweetened with sucrose)?

1 2 3 4 5 6 7 M N Cup

How many times do you usually eat canned fruit (sweetened with juice)?

1 2 3 4 5 6 7 M N Cup

How many pears do you eat per week?

How many apples do you eat per week?

How many oranges do you eat per week?

How many bananas do you eat per week?

How many mussels you eat per week?

How many times you eat other types of fruit? Such as: watermelon, strawberry, kiwi, grape, peach 1 2 3 4 5 6 7 M N

Eggs and dairy products

How many eggs do you eat per week?

What kind of milk do you usually use?

1. Full-fat
2. Low fat
3. Skimmed
4. Soy milk
5. Goat milk
6. Milk Kerlat
7. Do not use milk

What is the total amount of milk used per day (milk drinks / tea in coffee / and with cereals)?

1. Do not use milk
2. Half a liter or less
3. Between half a liter and one liter
4. One liter or more

How many times are you having yogurt?

1 2 3 4 5 6 7 M N

What kind yogurt that is usually used?

1. Full-fat
2. Low fat
3. Skimmed

What is the total amount of cream used per week?

The following can be used to determine the amount covered in the week (large pack = 300 grams, a small packet = 150 gm, 1 spoon eating = 20 gm)

What is the amount of cheese (except Al-Kareesh cheese) used per week?

How many times do you eat with Al-Kareesh cheese?

1 2 3 4 5 6 7 M N

How many times do you eat spread cheese?

1 2 3 4 5 6 7 M N

How many times do you eat labanah?

1 2 3 4 5 6 7 M N

Fat

What is the amount of butter used per week?Gram

The following can be used to determine the amount covered (full pack = 250 grams, a teaspoon = 5 gm, eating spoon = 15 gm)

How often do you eat food fried?
(Such as: eggs, tomatoes, onions, eggplant, fish, chicken)

1 2 3 4 5 6 7 M N

What is the commercial name of butter / oils used in frying?

What is the commercial name of butter / oils used for frying potatoes?

What is the commercial name of butter / oils used for food roasting food?

What is the commercial name of butter / oils used in preparation of cake?

What is the commercial name of oil used for preparing pastry / Tarts in house?

Drinks

How many cups of tea do you drink per day?

How much sugar added per cup? teaspoon

How many cups of coffee do you drink per day?

How much sugar added per cup? teaspoon

How many times do you drink fruit juice (such as Tropicana)?

1 2 3 4 5 6 7 M N

How many times do you drink fresh juice?

1 2 3 4 5 6 7 M N

How many times do you drink fruit drinks (such as Sun Top)?

1 2 3 4 5 6 7 M N

How many times do you drink soft drinks?

1 2 3 4 5 6 7 M N

How many times do you drink diet soft drinks?

1 2 3 4 5 6 7 M N

How many times do you drink energy drinks?

1 2 3 4 5 6 7 M N

How many times do you drink a glass of water?

1 2 3 4 5 6 7 M N

Soups and sauces

How many times do you eat the following soups and sauces? specify the quantity

Vegetable Soup
1 2 3 4 5 6 7 M N

Cream soup (chicken, mushroom, tomato)
1 2 3 4 5 6 7 M N

Lentils soup
1 2 3 4 5 6 7 M N

Sauces (curry, sweet and sour)
1 2 3 4 5 6 7 M N

Mayonnaise (with salad or fries)
1 2 3 4 5 6 7 M N

Ketchup (with sandwiches or fries)
1 2 3 4 5 6 7 M N

Salad cream
1 2 3 4 5 6 7 M N

Salad Sauces (French / Italian / Blue cheese)
1 2 3 4 5 6 7 M N

Height and weight measurement

Height? Cm
weight? Kg

What is the physical activity required by your job?

1. Non-active
2. Average activity
3. Very active
4. I do not work

What is the extent of physical activity in your leisure time?

1. Non-active
2. Average activity
3. Very active

Do you use vitamin tablets?

1. Yes, now, select how long you use?
2. Yes, in the past, specify the duration?
3. No

If the answer is yes, provide the type of tablets (name)?

Mussels

Type of Mussels

1. Sukary
2. Nabot Saif
3. Sultana
4. Khalas
5. Other

Quantity of Mussels

Quantity in morning # 1 2 3 4 5 6 7 M N

Quantity in noon # 1 2 3 4 5 6 7 M N

Quantity in night # 1 2 3 4 5 6 7 M N

Did you eat Mussels the day before blood withdrawal?

1. Yes
2. No

Water

Type of drinking water

1. Tap water
2. Water from tanks
3. Bottled water

Type of water used in cooking

1. Tap water
2. Water from tanks
3. Bottled water

If you are using bottled water, specify the type

- 1
 - 2
 - 3
-

Appendix 3: Agreement between the Saudi collaborators and Warwick Medical School for the purpose of this project

May 2011

AGREEMENT

Between

Biomarkers Research Program (BRP), College of Science, King Saud University (KSU)
PO Box 2455, Riyadh 11451, Kingdom of Saudi Arabia

AND

Metabolic Health Group, Clinical Sciences Research Institute (CSRI)
Warwick Medical School, University of Warwick, Coventry
CV4 7AL, United Kingdom

This agreement is between BRP (First Party), represented by **Dr. Nasser Al-Dagheri**, deputy director, AND the Metabolic Health Group, CRIS (Second Party), represented by **Prof. Sudhesh Kumar, Dr. Saverio Stranges and Dr. Karen Rees**. This agreement describes the nature of collaboration in supervising **Miss. Lena Al-Khudairy** in her PhD thesis at the University of Warwick.

Since BRP will be actively involved in the PhD project of MISS. Lena Al-Khudairy entitled “Diet Composition and Type 2 Diabetes Mellitus in Saudi Arabia”, a summary of which is provided; the following agreement was reached by the above mentioned parties with regards to the involvement of BRP.

The study intends to perform both cross-sectional and longitudinal analyses to examine the association between selected dietary components and Type 2 Diabetes Mellitus (T2DM) in a cohort of 3248 Saudi adults (2519 non T2DM).

Responsibilities of the 1st Party:

1. BRP will analyze frozen serum samples that were collected and stored in 2009 for a number of biomarkers (selenium, vitamin D, specific insulin) for a subsample at an agreed cost.
2. BRP will provide dietary data, demographics and baseline blood results of the 3248 Saudi adults from the master database of BRP.
3. BRP is not responsible for costs except for that which been agreed in writing.

Responsibilities of the 2nd Party:

1. It is the responsibility of Miss. Lena Al-Khudairy and her group to find, recruit, and follow up the patients.
2. Miss. Lena Al-Khudairy will fund the expenses related to her thesis (Funded by The Ministry of Higher Education).

Benefits:

1. The BRP Group (Dr. Nasser Al-Dagheri, Prof. Omar Al-Attas, Dr. Majed Alokail and Dr. Khalid Alkharfy) will be included as co-authors in all the publications that will come out from this study.
2. The information provided by BRP from its master database is not to be used for other studies without the permission of the 1st Party.

Agreed and Approved:

Dr. Nasser Al-Dagheri

1st Party

On behalf of BRP



Prof. Sudhesh Kumar

2nd Party

On behalf of CSRI Metabolism Group



Dr. Saverio Stranges

2nd Party

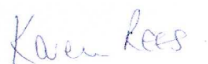
On behalf of CSRI Metabolism Group



Dr. Karen Rees

2nd Party

On behalf of CSRI Metabolism Group



Appendix 4: Ethical approval for the Biomarkers Screening Survey (2009) in English and Arabic copy

College of science

King Saud University

Ministry of Higher Education

Kingdom of Saudi Arabia

Dr. Omar Bin Salem Al Attas

Peace, mercy and blessing of God

In the third meeting of Ethics Research Committee on 03/05/2009 at the meeting room in the Chemistry department we discussed the research proposal 'Biomarkers Screening Program- Riyadh Cohort, of Drs Omar Bin Salem Al Attas, Nasser Bin Mohammed Al Dagheri, Majed Al Ogail, and Khalid Al Kharfy.

Decision: We decided to grant you approval after the required amendments.

Kindly provide a semi annual progress report, and a final report of the research results.

Kind Regards,

Chair of Ethics Committee

Dr. Nasser Bin Mohammed Al Dagheri

بسم الله الرحمن الرحيم



المملكة العربية السعودية
وزارة التعليم العالي
جامعة الملك فهد
كلية العلوم

الرقم: د. محمد

التاريخ: ١٦ / ٥ / ١٤٣٠ هـ

المرفقات:

الموضوع:

حفظه الله

سعادة الدكتور / عمر بن سالم العطاس

السلام عليكم ورحمة الله وبركاته

تم في الاجتماع الثالث للجنة أخلاقيات البحوث العلمية الحيوية المنعقدة يوم الأحد الموافق ٨ / ٥ / ١٤٣٠ هـ الموافق ٣ / ٥ / ٢٠٠٩ م في قاعة الاجتماعات بقسم الكيمياء الحيوية مناقشة بحث الدكتور / عمر بن سالم العطاس والدكتور / ناصر بن محمد الداغري والدكتور / ماجد العقيل والدكتور خالد الخرفي تحت عنوان : " مسح المؤشرات الحيوية - خبرة الرياض".

القرار: الموافقة على إجراء الدراسة بعد إجراء التعديلات المطلوبة .

كما أرجو إفادتنا بتقرير نصف سنوي عن المستجدات خلال البحث ، وتقرير نهائي بعد انتهاء البحث.
مع خالص الشكر والتقدير

ودمتم بخير، ،

رئيس لجنة

أخلاقيات البحوث العلمية الحيوية

د. ناصر بن محمد الداغري

Appendix 5: Comparison* between participants with ($n = 2631$) and without dietary data ($n = 529$)

Variable	No dietary data	With dietary data	<i>p</i>
<i>n</i>	529	2631	
Age (years)	37.52±15.42	40.80±15.47	<0.001
Sex(%)			
Females	48.0%	48.7%	0.790
Males	52.0%	51.3%	
Weight (kg)	72.84±17.94	76.63±17.32	<0.001
BMI (kg/m ²)	28.49±7.78	29.16±6.36	0.041
WC (cm)	87.04±21.77	94.11±15.83	<0.001
WHR	0.90±0.41	0.90±0.12	0.846
SAD (cm)	23.93±14.56	23.90±8.19	0.954
Systolic (mmHg)	117.76±16.86	120.26±14.41	0.003
Diastolic (mmHg)	75.39±9.90	77.41±8.62	<0.001
FPG (mmol/L)	5.52±1.28	6.32±1.45	<0.001
TC (mmol/L)	4.91±1.13	5.08±1.21	0.003
TG (mmol/L)	2.33±1.36	2.58±1.40	<0.001
LDL-C (mmol/L)	3.51±1.02	3.40±1.05	0.032
HDL-C (mmol/L)	0.74±0.29	0.86±0.34	<0.001
Diabetes (%)			
NDM	77.9%	60.2%	<0.001
PDM	12.5%	10.5%	
T2DM	9.6%	29.3%	
Family history of diabetes			
No history	30.7%	17.5%	<0.001
First degree	39.4%	44.9%	
Second degree	4.0%	14.1%	
Both first and second	25.9%	23.4%	

*Mean values ± SD or percentages (%); **BMI** indicates body mass index; **WC** indicates waist circumference; **WHR** indicates waist to hip ration (waist (cm)/hips (cm)); **SAD** indicates sagittal abdominal diameter in cm; **FPG** indicates fasting plasma glucose; **TC** indicates total cholesterol; **TG** indicates triglycerides; **LDL-C** indicates low density lipoprotein cholesterol; **HDL-C** indicates high density lipoprotein cholesterol; **NDM**: non diabetics (FPG < 6.1 mmol/L, < 110 mg/dL), **PDM**: pre-diabetes (self-reported pre-diabetes and/or FPG 6.1 -6.9 mmol/L, 110 to 125 mg/dL), **T2DM**: type 2 diabetes mellitus (self-reported T2DM and/or FPG ≥7.0 mmol/L; ≥126 mg/dL); **Family history of diabetes**: 1st degree includes father, mother, siblings or children. 2nd degree includes uncle, aunt, grandparents or grandchildren.

Appendix 6: Comparison* between participants that were aware of their diabetes and unaware of their diabetes at the time of the 2009 survey for anthropometric measures

Variable	Aware T2DM	Unaware T2DM	<i>p</i>
<i>n</i>	770	282	
Age (years)	54.07±12.29	45.95±14.25	<0.001
Sex (%)			
Females	40.4%	45.4%	0.174
Males	59.6%	54.6%	
Weight (kg)	80.87±16.06	80.36±15.99	0.674
BMI (kg/m ²)	30.95±6.14	30.57±6.08	0.412
BMI categories			
Underweight	1.2%	0.4%	0.034
Normal weight	11.0%	17.6%	
Overweight	36.8%	31.1%	
Obese	50.9%	50.9%	
WC (cm)	101.41±13.82	97.57±14.39	0.001
Hips (cm)	107.88±14.80	105.71±16.04	0.081
SAD (cm)	25.39±6.10	24.48±6.76	0.097
WHR	0.95±0.13	0.92±0.10	0.017

* Percentages (%) or mean values ± SD.

p statistical difference between diabetes groups.

BMI indicates body mass index; **BMI categories**: Underweight < 18.5 kg/m², Normal weight 18.5-24.99 kg/m², Overweight ≥ 25 kg/m², Obese ≥ 30 kg/m²; **WC** indicates waist circumference; **SAD** indicates sagittal abdominal diameter in cm; **WHR** indicates waist to hip ration (waist (cm)/hips (cm));

Appendix 7: Odds ratio for T2DM prevalence: NDM vs. Unaware of T2DM (at the time of the 2009 survey) in comparison to NDM vs. T2DM (both aware and unaware of T2DM)

In the overall sample

	18.5-24.99 (Normal)	25.00-29.99 (Overweight)	≥30.00 (Obese)	<i>p</i> for trend
BMI (kg/m ²)				
Model 5 (NDM vs. Unaware)	1	1.03 (0.6-1.7)	1.60 (0.9-2.6)	0.021
Model 5 (NDM vs. T2DM)	1	1.39 (0.9-2.1)	2.08 (1.4-3.0)	<0.001
WC	I	II	III	
Model 5 (NDM vs Unaware)	1	2.07 (1.2-3.3)	2.08 (1.2-3.3)	0.005
Model 5 (NDM vs. T2DM)	1	2.18 (1.5-3.1)	2.41 (1.6-3.4)	<0.001

In the sex scarified sample

Variable	Females				Males			
BMI (kg/m ²)	18.5-24.99 (Normal)	25.00-29.99 (Overweight)	≥30.00 (Obese)	<i>p</i> for trend	18.5-24.99 (Normal)	25.00-29.99 (Overweight)	≥30.00 (Obese)	<i>p</i> for trend
Model 5 (NDM vs. Unaware)	1	1.39 (0.5-3.6)	2.71 (1.1-6.4)	0.006	1	0.88 (0.4-1.6)	1.00 (0.5-1.8)	0.913
Model 5 (NDM vs. T2DM)	1	2.47 (1.1-5.2)	3.68 (1.8-7.4)	<0.001	1	1.00 (0.6-1.6)	1.41 (0.8-2.2)	0.077
WC (cm)	I	II	III	<i>p</i> for trend	I	II	III	<i>p</i> for trend
Model 5 (NDM vs Unaware)	1	1.55 (0.7-3.1)	2.07 (1.03-4.1)	0.039	1	1.26 (0.67-2.37)	1.51 (0.81-2.80)	0.184
Model 5 (NDM VS. T2DM)	1	2.02 (1.1-3.4)	2.19 (1.2-3.7)	0.007	1	1.72 (1.1-2.7)	1.99 (1.2-3.1)	0.006

Unaware indicates participants unaware of their diabetes at the time of the 2009 survey; **Aware** indicates participants aware of their diabetes at the time of the 2009 survey.

Model summery in the overall sample: adjusted for age, sex, marital status, education level, family history of diabetes, physical activity, caloric intake.

Model summery in sex stratified sample: adjusted for age, marital status, education level, family history of diabetes, physical activity, caloric intake.

Appendix 8: Ethical approval from the Ethics Committee of the College of Medicine Research Centre, King Saud University, Riyadh, KSA

Kingdom of Saudi Arabia
Ministry of Higher Education
King Saud University
College of Science

To Miss Lena Al Khudairy

Peace, mercy and blessing of God

We would like to inform you that the Ethics Research Committee at the College of Science has discussed your research proposal "Macro and Micronutrient status in Saudi adults with and without Type 2 Diabetes Mellitus" on Sunday 11.12.2011.

The Ethics Research Committee granted you approval.

Kind Regards,

Chair of Ethics Committee

Dr. Nasser Bin Mohammed Al Dagheri

بسم الله الرحمن الرحيم



المملكة العربية السعودية
وزارة التعليم العالي
جامعة الملك فهد
كلية العلوم

الرقم: ٨/٥٥/٢٦٦٩٦

التاريخ: ١ / ٩ / ١٤٤٣ هـ

المرفقات:

الموضوع:

حفظه الله

سعادة الأستاذة/ ليلى الخضيرى

السلام عليكم ورحمة الله وبركاته

نفيد سعادتكم بأن لجنة أخلاقيات البحوث الحيوية العلمية بكلية العلوم ناقشت في الاجتماع الأول يوم الأحد الموافق ١٦ / ١ / ١٤٣٣ هـ الموافق ١١ / ١٢ / ٢٠١١ م البحث المرسل من سعادتكم تحت عنوان " Macro and micronutrient status in Saudi adults with " and without type 2 diabetes mellitus .

وقد وافقت اللجنة على المشروع.

وتقبلوا خالص تحياتي وتقديري ، ، ،

ودمتم بخير ، ، ،

رئيس لجنة أخلاقيات البحوث الحيوية العلمية

د. ناصر بن محمد الداغري

Appendix 9: Ethical approval from the Biomedical Research Ethics Committee of the University of Warwick



Appendix 10: The food frequency questionnaire administered in the calibration study

If you eat the food every day select No.7

If you eat the food three days a week select No. 3

If you eat food once every two weeks or once a month select **M**

If you rarely eat food or never select **N**

1 2 3 4 5 6 7 M N

!

As you will be asked to determine the amount of food, please identify the quantity in weight (gram) or cup or spoon or number of pieces, e.g. quantity of milk (cup), and meat (gm), sugar (teaspoon).

Bread

Usually, how many times do you eat **white bread** (bakery)?

1 2 3 4 5 6 7 M N

How many pieces (1/4 loaf) eat during the day?

.....

Select the size of a loaf of bread? (Please choose the appropriate answer)

1. Large

2. Medium

3. Small

Usually, how many times do you eat **brown bread** (bakery)?

1 2 3 4 5 6 7 M N

How many pieces (1/4 loaf) eat during the day?

.....

Select the size of a loaf of bread? (Please choose the appropriate answer)

1. Large

2. Medium

3. Small

Usually, how many times do you eat the **white bread "Shami"**?

1 2 3 4 5 6 7 M N

How many pieces (1/4 loaf) eat during the day?

.....

Select the size of a loaf of bread? (Please choose the appropriate answer)

1. Large

2. Medium

3. Small

Usually, how many times do you eat **brown bread "Shami"**?

1 2 3 4 5 6 7 M N

How many pieces (1/4 loaf) eat during the day?

.....

Select the size of a loaf of bread? (Please choose the appropriate answer)

1. Large
2. Medium
3. Small

Usually, how many times do you eat **white toast slices**?

1 2 3 4 5 6 7 M N

How many slices you eat during a day?

.....

Select the size of Toast? (Please choose the appropriate answer)

1. Jumbo / large
2. Normal

Usually, how many times do you eat **brown toast slices**?

1 2 3 4 5 6 7 M N

How many slices you eat during a day?

.....

Select the size of Toast? (Please choose the appropriate answer)

1. Jumbo / large
2. Normal

Usually, how many times do you eat Shaboura?

1 2 3 4 5 6 7 M N

What is the type of Shaboura?

1. Shaboura with sesame
2. Wheat Shaboura
3. Brown Shaboura
4. Brown Shaboura with bran and cereals
5. brown Shaboura with cereals without bran
6. Shaboura with Mussels

What is the amount of shaboora eaten per occasion?

.....

Select the size of a piece of Shaboura? (Please choose the appropriate answer)

1. Large
2. Medium
3. Small

Eggs and dairy products

How many eggs do you eat per week?

What kind of milk do you usually use?

1. Full-fat
2. Low fat
3. Skimmed
4. Soy milk
5. Goat milk
6. Milk Kerlat
7. Do not use milk

What is the total amount of milk used per day (milk drinks / tea in coffee / and with cereals)?

1. Do not use milk
2. Half a liter or less
3. Between half a liter and one liter
4. One liter or more

Fruits

How many pears do you eat per week?

How many apples do you eat per week?

How many oranges do you eat per week?

How many bananas do you eat per week?

How many mussels you eat per week?

Drinks and sugar

How many cups of tea do you drink per day?

How much sugar added per cup? teaspoon

How many cups of coffee do you drink per day?

How much sugar added per cup? teaspoon

How many teaspoons of sugar / honey do you add to cereals?

Mussels

Type of Mussels

1. Sukary
2. Nabot Saif
3. Sultana
4. Khalas
5. Other

Quantity of Mussels

Quantity in morning	#	1	2	3	4	5	6	7	M	N
---------------------	---	---	---	---	---	---	---	---	---	---

Quantity in noon	#	1	2	3	4	5	6	7	M	N
------------------	---	---	---	---	---	---	---	---	---	---

Quantity in night	#	1	2	3	4	5	6	7	M	N
-------------------	---	---	---	---	---	---	---	---	---	---

Appendix 11: The 24 hour questionnaire used in the calibration study

Was yesterday a typical day of your eating habits?

☐ **Yes**☐ **No**[illegible]

Appendix 12: Comparison* between participants that were unaware of T2DM and aware of T2DM

Variable**	Unaware of T2DM	Aware of T2DM	<i>p</i>
White bread	2.37±2.37	2.02±2.28	0.031
Brown bread	1.52±1.77	1.79±2.14	0.002
Egg	1.56±1.26	1.50±1.23	0.054
Milk	2.61±1.08	2.63±1.09	0.827
Fruits	2.62±1.38	2.73±1.39	0.213
Dates	1.86±1.38	1.87±1.42	0.765
Sugar/honey	4.81±2.47	3.09±2.70	<0.001
Tea	3.30±1.63	3.35±1.77	0.681
Coffee	3.55±2.04	3.53±1.88	0.884

*Mean values±SD

** Serving/day

Appendix 13: The pilot study questionnaire

Section one

1. Does 'healthy eating' matter to you?

- a. Yes
- b. No

If yes why? (free text response)

.....

.....

.....

If not, why not? (free text response)

.....

.....

.....

2. Have you ever seen a dietician?

- a. Yes
- b. No

If yes why? (free text response)

.....

.....

.....

If not, why not? (free text response)

.....

.....

.....

3. Do you know which foods people should eat less of to reduce the risk of getting diabetes?

- a. Yes
- b. No

If yes, could you please list? (free text response)

.....

.....

.....

Section two Al Quaiz et al. (2009) questionnaire

Do you have type 2 diabetes?

- a. Yes.
- b. No.

(For people with no diabetes)

Statement	0– No never	1-No sometimes	2-Yes sometimes	3-Yes always
<i>1. I lack the motivation to follow a healthy diet</i>				
<i>2. I cannot resist traditional food</i>				
<i>3. I do not want to follow a healthy diet because I previously failed to do so</i>				
<i>4. I don't want to change my eating habits because I do not have any health problems</i>				
<i>5. I do not believe that there is a relationship between unhealthy diet and diabetes</i>				
<i>6. I do not need to eat fruits and vegetables because I take vitamin supplements</i>				
<i>7. I cannot follow a healthy diet because I stay away from home for most of the day</i>				
<i>8. I was not exposed to educational programs that can educate me about healthy eating</i>				
<i>9. I do not have enough time to prepare healthy meals</i>				
<i>10. I do not follow a healthy diet because I will feel deprived when I look at what others are eating</i>				
<i>11. My family do not help/support me to follow a healthy diet</i>				
<i>12. Social gatherings/commitments stops me from following a healthy diet</i>				
<i>13. Fast food media influence my eating habits</i>				
<i>14. I like fast food because it is easy to get</i>				
<i>15. I do not buy healthy food because it is expensive and has a short shelf life</i>				

(For people with type 2 diabetes)

Statement	0– No never	1-No sometimes	2-Yes sometimes	3-Yes always
1. I lack the motivation to follow a healthy diet				
2. I cannot resist traditional food				
3. I do not want to follow a healthy diet because I previously failed to do so				
4. I don't want to change my eating habits because I do not believe I need to				
5. I do not believe that there is a relationship between unhealthy diet and diabetes				
6. I do not need to eat fruits and vegetables because I take vitamin supplements				
7. I cannot follow a healthy diet because I stay away from home for most of the day				
8. I was not exposed to educational programs that can educate me about healthy eating				
9. I do not have enough time to prepare healthy meals				
10. I do not follow a healthy diet because I will feel deprived when I look at what others are eating				
11. My family do not help/support me to follow a healthy diet				
12. Social gatherings/commitments stops me from following a healthy diet				
13. Fast food media influence my eating habits				
14. I like fast food because it is easy to get				
15. I do not buy healthy food because it is expensive and has a short shelf life				

Please note that the third question is rephrased to fit within the diabetes context

Section three

Do you agree with the following statements? Sabra et al. (2010) questionnaire	Yes	No
<i>1. People with diabetes that are on medications can eat any type of food</i>		
<i>2. Dates are very important for the health of people with diabetes</i>		
<i>3. Honey is good for people with diabetes</i>		
<i>4. All carbohydrates should be removed from the diabetic diet</i>		
<i>5. Bitter food will reduce high blood glucose levels</i>		
<i>6. Dried bread contains less sugar than normal bread</i>		
<i>7. Regular intake of snacks between meals is essential for adult diabetic patients</i>		
Developed statements for this study:	Yes	No
8. Beans, lentils and corn do not contain carbohydrates		
9. Fresh fruit juice is better than whole fruit for people with diabetes		
10. Excess weight does not affect diabetes		
11. Vegetables will not help in regulating sugar levels in people with diabetes		
12. There is only one diet people with diabetes should follow		
13. Portion size is not important for people with diabetes		

Appendix 14: The modified questionnaire used in this project

Section one: Developed for this current study

1. How would you describe a “healthy diet”? (free text response)

.....
.....
.....

2. Does “healthy eating” matter to you?

- a. Yes
- b. No

If yes why? (free text response)

.....
.....
.....

If not, why not? (free text response)

.....
.....
.....

3. Have you ever seen a dietician?

- a. Yes
- b. No

If yes why? (free text response)

.....
.....
.....

If not, why not? (free text response)

.....
.....
.....

4. Do you know which foods people should eat less of to reduce the risk of getting diabetes?

- a. Yes
- b. No

If yes, could you please list? (free text response)

.....
.....
.....

5. Do you know which foods people should increase to reduce the risk of getting diabetes?

- a. Yes
- b. No

If yes, could you please list? (free text response)

.....

.....

6. Do you know what Carbohydrates are?

- a. Yes
- b. No

If yes, could you please give some examples? (free text response)

.....

Section two: Barriers to healthy eating by Al Quaiz et al. (2009)

Do you have type 2 diabetes?

- a) Yes
- b) No

(For people with no diabetes)

Statement	0– No never	1-No sometimes	2-Yes sometimes	3-Yes always
<i>1. I lack the motivation to follow a healthy diet</i>				
<i>2. I cannot resist traditional food</i>				
<i>3. I do not want to follow a healthy diet because I previously failed to do so</i>				
<i>4. I don't want to change my eating habits because I do not have any health problems</i>				
<i>5. I do not believe that there is a relationship between unhealthy diet and diabetes</i>				
<i>6. I do not need to eat fruits and vegetables because I take vitamin supplements</i>				
<i>7. I cannot follow a healthy diet because I stay away from home for most of the day</i>				
<i>8. I was not exposed to educational programs that can educate me about healthy eating</i>				
<i>9. I do not have enough time to prepare healthy meals</i>				
<i>10. I do not follow a healthy diet because I will feel deprived when I look at what others are eating</i>				
<i>11. My family do not help/support me to follow a healthy diet</i>				
<i>12. Social gatherings/commitments stops me from following a healthy diet</i>				
<i>13. Fast food media influence my eating habits</i>				
<i>14. I like fast food because it is easy to get</i>				
<i>15. I do not buy healthy food because it is expensive and has a short shelf life</i>				

(For people with type 2 diabetes)

<i>Statement</i>	<i>0–No never</i>	<i>1–No sometimes</i>	<i>2–Yes sometimes</i>	<i>3–Yes always</i>
<i>1. I lack the motivation to follow a healthy diet</i>				
<i>2. I cannot resist traditional food</i>				
<i>3. I do not want to follow a healthy diet because I previously failed to do so</i>				
<i>4. I don't want to change my eating habits because I do not believe I need to</i>				
<i>5. I do not believe that there is a relationship between unhealthy diet and diabetes</i>				
<i>6. I do not need to eat fruits and vegetables because I take vitamin supplements</i>				
<i>7. I cannot follow a healthy diet because I stay away from home for most of the day</i>				
<i>8. I was not exposed to educational programs that can educate me about healthy eating</i>				
<i>9. I do not have enough time to prepare healthy meals</i>				
<i>10. I do not follow a healthy diet because I will feel deprived when I look at what others are eating</i>				
<i>11. My family do not help/support me to follow a healthy diet</i>				
<i>12. Social gatherings/commitments stops me from following a healthy diet</i>				
<i>13. Fast food media influence my eating habits</i>				
<i>14. I like fast food because it is easy to get</i>				
<i>15. I do not buy healthy food because it is expensive and has a short shelf life</i>				

Please note that the third question is rephrased to fit within the diabetes context

Section three: Modified version of dietary misconceptions in T2DM by Sabra et al. (2010):

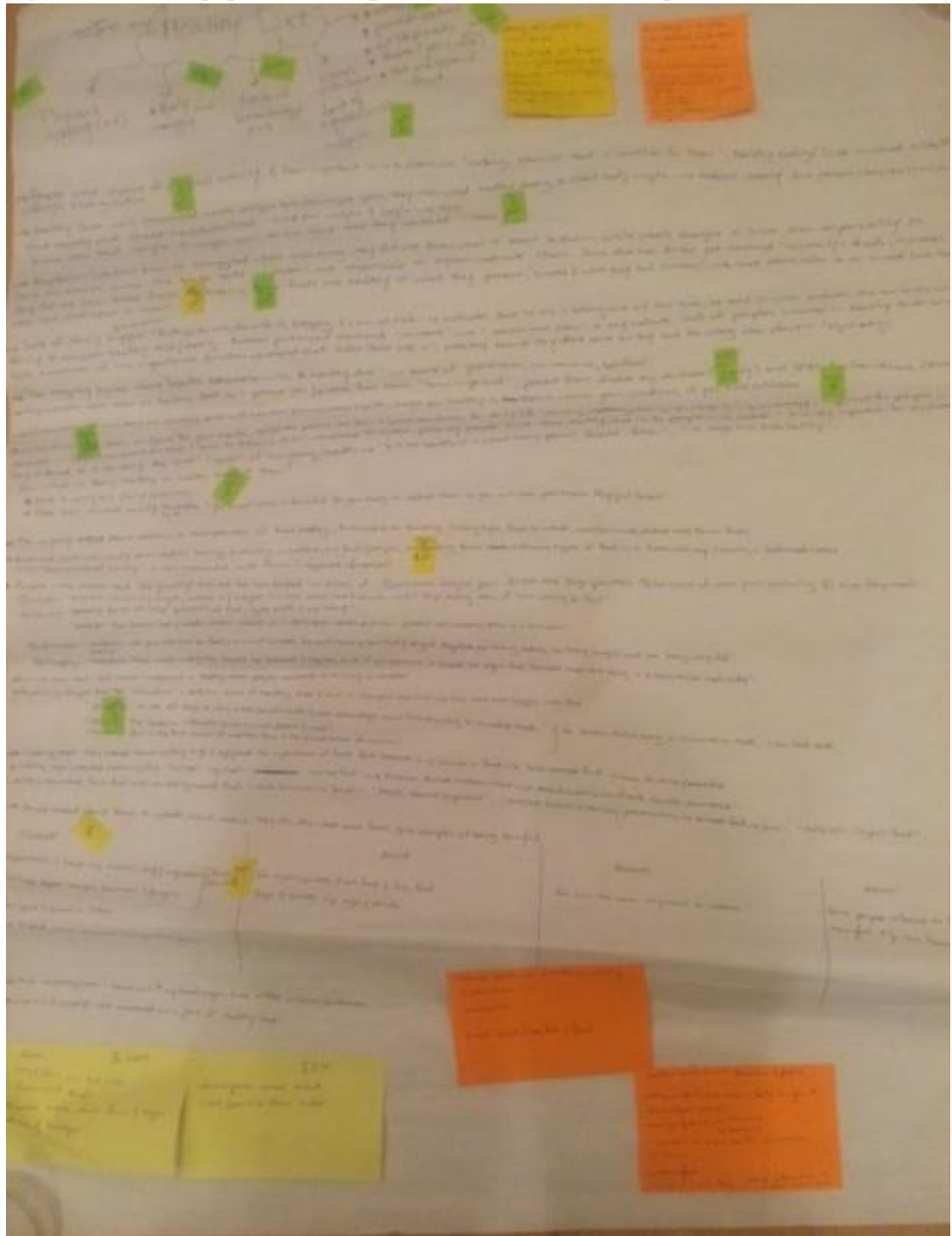
Do you agree with the following statements?	Yes	No
<i>1. People with diabetes that are on medications can eat any type of food</i>		
<i>2. Dates are very important for the health of people with diabetes</i>		
<i>3. Honey is good for people with diabetes</i>		
<i>4. All carbohydrates should be removed from a diabetic diet</i>		
<i>5. Bitter food will reduce high blood glucose</i>		
<i>6. Toasted bread contains less sugar than normal bread</i>		
<i>7. Regular intake of snacks between meals is essential for adults with type 2 diabetes</i>		
<i>8. Beans, lentils and corn do not contain carbohydrates</i>		
<i>9. Fresh fruit juice is better than whole fruit for people with diabetes</i>		
<i>10. Abdominal obesity is not associated with diabetes</i>		
<i>11. Vegetables will not help in regulating sugar levels in people with diabetes</i>		
<i>12. There is only one diet people with diabetes should follow</i>		
<i>13. Portion size is not important for people with diabetes</i>		

Appendix 15: Visual examples on the process of qualitative analysis

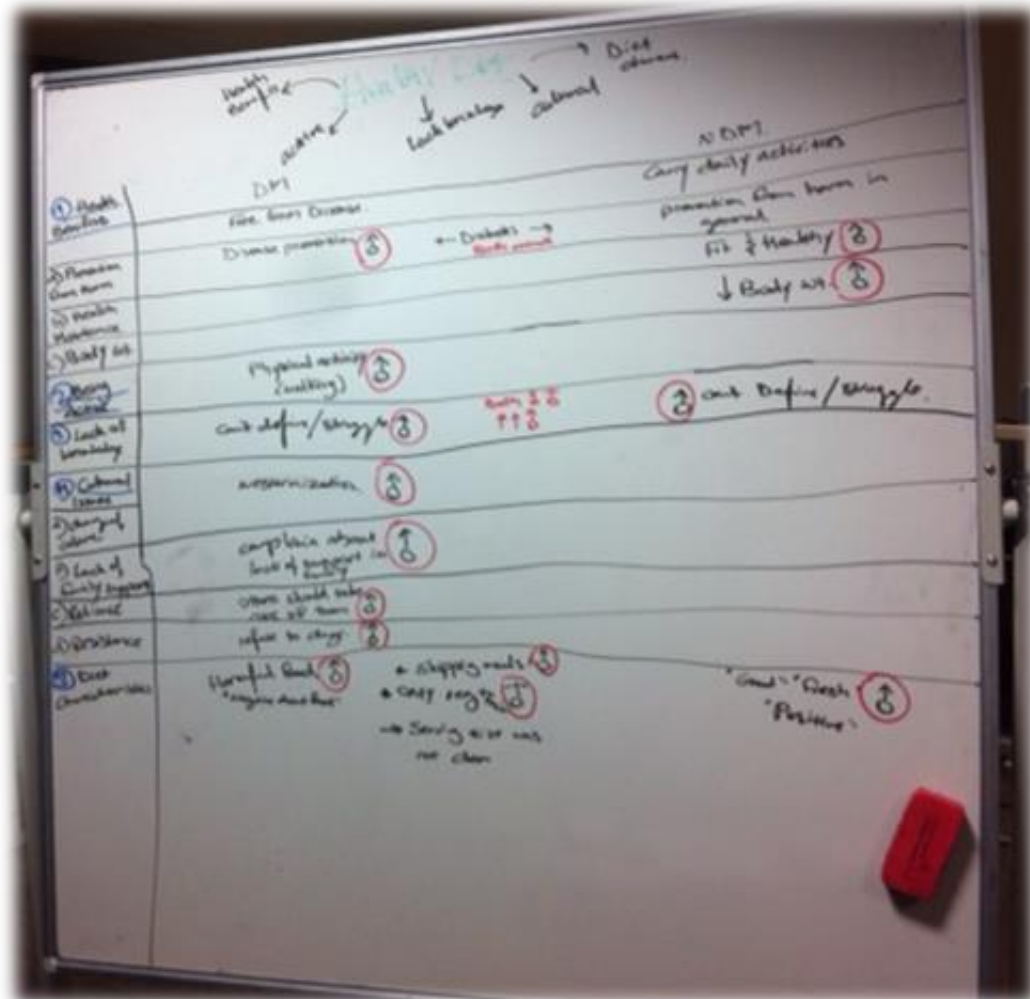
e.g. One sheet of paper for all the data (overall data and codes)

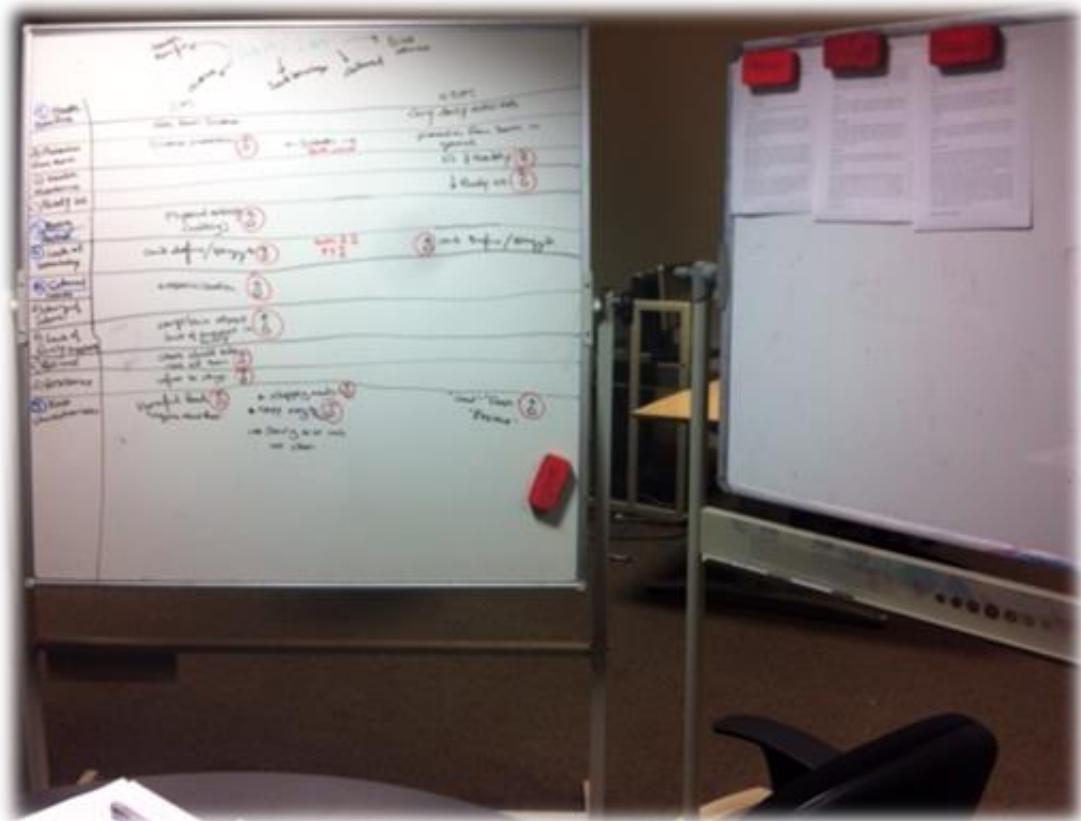


e.g. Ones sheet of paper for each question and constant comparison



e.g. Constant comparison, taking notes, applying theoretical and asking questions





Health Benefits	Does it Matter?	
	DM	NDM
① Disease prevention	Precious health ♂	Strong, fit, mental well-being ♂
② Health maintenance	♂	♂
③ Child health	♂	♂
④ Cultural Issues	♂	♂
⑤ Change of culture	♂	♂
⑥ Social pressure	♂	♂
⑦ Resistance to change	♂	♂

Additional notes on the table:

- DM:**
 - ① Precious health ♂
 - ② ♂
 - ③ ♂
 - ④ ♂
 - ⑤ ♂
 - ⑥ ♂
 - ⑦ ♂
- NDM:**
 - ① Strong, fit, mental well-being ♂
 - ② ♂
 - ③ ♂
 - ④ ♂
 - ⑤ ♂
 - ⑥ ♂
 - ⑦ ♂

Other notes on the table:

- DM:**
 - ① Precious health ♂
 - ② ♂
 - ③ ♂
 - ④ ♂
 - ⑤ ♂
 - ⑥ ♂
 - ⑦ ♂
- NDM:**
 - ① Strong, fit, mental well-being ♂
 - ② ♂
 - ③ ♂
 - ④ ♂
 - ⑤ ♂
 - ⑥ ♂
 - ⑦ ♂

